

---

Dear subscriber,

## Issue 13

Welcome to the October issue of the Human Tissue Authority's e-newsletter.

The e-newsletter is the main way that we communicate changes to our regulatory policy, so it is essential reading if you work in one of the sectors that we regulate. We also use the e-newsletter to let you know about new advice and guidance, and where you can find this on our website.

In this issue, you can find out about our five summary inspection reports and guide to key messages which were launched at our annual report back meeting in September. This issue also includes information about how to have your say on the HTA website review and gives an update on our current consultations. Two new policies are also available on our website, on the sale of bodies and body parts, and regulatory enforcement.

If you have any comments or queries about the issues raised in this e-newsletter, or any ideas for items that you would like to see in the future, please contact us at [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk).

---

## Have your say on the HTA website review

We are carrying out a survey to find out your views about the HTA website. This is your opportunity to have a say on the information that we provide on the website and how easy it is to find it; and to give us your views on how we can improve the site in the future.

We would really appreciate your input into the survey, as the more people that respond, the more the results will help us to improve the website for everyone that uses it.

The survey should take no more than 10 minutes of your time to complete.

[Complete the HTA website survey now](#)

The deadline for completing the survey is Friday 31 October.

If you have any questions about the survey please contact Andy Thornley, Communications Officer on 020 7211 3416 or email [andy.thornley@hta.gov.uk](mailto:andy.thornley@hta.gov.uk)

---

## Summary inspection reports launched

We recently launched five summary inspection reports, one for each of the sectors that we license and inspect – anatomy, human application, post-mortem, public display and research. The reports summarise the key learning points from the HTA's experience of regulating over the last two years. They are essential reading if you work in any of these sectors as they provide information on what lessons can be learnt and how standards can be improved. We very much hope that you will use this information to reflect on standards in your own

establishments.

The reports show that professionals have a good understanding of the need to seek consent from the person who donated the tissue. They also show that those who use human tissue are willing to work within HTA requirements, and that many sectors are performing well. Areas for improvement are also highlighted.

[The five reports can be downloaded](#) from our website. We would really appreciate your feedback on these reports to help us improve them in future years. If you have comments about a particular report, please contact the [Head of Regulation](#) relevant to your sector.

---

## Consultations

### Codes of practice consultation

The consultation on our revised codes of practice is running until 14 November 2008. Seven of our codes of practice are being revised to reflect our experience of regulation; and we have also produced an entirely new code on research. This is your opportunity to give us your views on the content of the revised codes.

[Read the codes and find out how to respond to the consultation](#) on our website. There are two consultation events, one which took place in Newcastle on 16 October and one in London on 22 October, which focus on the research, post-mortem and disposal codes.

If you have any questions about the consultation process, please contact Rosanna Bate, Policy Officer: [rosanna.bate@hta.gov.uk](mailto:rosanna.bate@hta.gov.uk) or 020 7211 3414.

### Licence fees consultation

We will be starting a consultation on our licence fee structure towards the end of the year. We would value your feedback on the proposed fee levels in the consultation.

Details about the proposed fee levels for each sector and on how to respond to the consultation will be available in the consultations section of our website. We will also be contacting all Designated Individuals and Licence Holders directly to inform them about the consultation.

If you have any questions about the consultation process, please contact Morounke Akingbola, Head of Resources: [morounke.akingbola@hta.gov.uk](mailto:morounke.akingbola@hta.gov.uk).

### Development of the HTA licensing process

The licences for the majority of sectors regulated by the HTA will come to the end of their terms in 2009. We therefore need to review our regulatory policy and process for renewing licences in the future. In order for this policy to be robust, it will need to take into account the experience and knowledge of the issues affecting each sector.

We have contacted stakeholders from each licensed sector to gather information that will inform this work. We are also holding a series of workshops to discuss the possible options for licence renewal in more detail.

If you would like any more information about this project please contact Christiane Niederlaender, Regulation Manager by email: [christiane.niederlaender@hta.gov.uk](mailto:christiane.niederlaender@hta.gov.uk).

---

## Guide to our key messages

We have recently launched a guide to our key messages, which explains in clear and accessible language what the HTA is and what we do.

If you work with patients and the public, this guide will help you to explain our roles and responsibilities. It

provides clear explanations about the different areas of our work, which you can use in your verbal and written communications. Please feel free to copy and use any text from the guide for your own use.

The guide does not provide regulatory advice or guidance for the professionals whom we regulate, as this is provided in our codes of practice and licensing guidance.

[You can download the guide to our key messages](#) from our website.

Please let us know if you have any comments about the guide or any suggestions for improving future editions. We would be very interested to see any examples of work where you have used the information in this guide. Please contact Andy Thornley, Communications Officer with any feedback: 020 7211 3416 or email [andy.thornley@hta.gov.uk](mailto:andy.thornley@hta.gov.uk).

---

## New HTA policies

### Policy on the sale of bodies and body parts

The HTA has recently published a statement on our position on the selling of human bodies, body parts and tissue. You can read the [policy on the sale of bodies and body parts](#) on our website.

### Regulatory enforcement policy

The HTA is responsible for making sure that licensed establishments comply with the requirements of the Human Tissue Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the HTA codes of practice. Where regulatory breaches are identified, appropriate regulatory action is taken in line with the HTA's enforcement policy.

You can read the [HTA's enforcement policy](#) on our website.

---

## Information for the human application sector

### Regulatory alert 003/2008

The HTA has issued a regulatory alert to all human application establishments. This regulatory alert relates to the emergence of West Nile Virus in the Bologna and Ferrara Districts of Italy.

This alert has been issued by the HTA in its role as Competent Authority under the European Union Tissues and Cells Directives.

This alert is to ensure that all establishments:

- are aware of the recent reports of West Nile Virus and can update their donor selection and evaluation criteria accordingly
- are aware of their obligations to ensure appropriate donor selection criteria are in place
- are aware of their obligations to report Serious Adverse Events and Serious Adverse Reactions to the HTA

Please visit the HTA website to read the [full regulatory alert on West Nile Virus](#).

---

## Information for the post-mortem sector

### Post-mortem working group

The HTA has a post-mortem working group which meets monthly to discuss issues relating to the sector. We have recently agreed that this group should be extended to include representatives from relevant professions, e.g. coroners, pathologists and anatomical pathology technicians, to work together on a specific project.

The findings of our inspections in the post-mortem sector showed that there is often uncertainty about families' wishes about disposal of material retained during a post-mortem, and that pathologists are not always aware that a coroner has completed his or her investigation. The main purpose of the extended working group will therefore be to consider how the communication pathway between coroners, pathologists and families could be improved, and to develop a protocol that may be used.

We will include more information about the work of this group in future issues of the e-newsletter. You can find out more about the results of our inspections in the post-mortem sector in the [post-mortem summary inspection report](#).

### Department of Health guidance on pandemic flu

The Department of Health (DH) has recently published [guidance on pandemic flu](#), which includes advice on 'end of life' care. The guidance requires that all Primary Care Trusts and Strategic Health Authorities produce emergency plans to deal with the deceased, in the event that a pandemic flu outbreak results in mass fatalities.

We would like to clarify that emergency temporary storage facilities that are set up to relieve undertakers are not subject to licensing by the HTA. In cases where there is doubt about the cause of death and post-mortem examination is authorised, the bodies may be stored for up to seven days in the emergency temporary storage facility before being moved to HTA-licensed premises.

If you would like any more information about this issue please email the DH's Pandemic Influenza Preparedness Team: [pandemicflu@dh.gsi.gov.uk](mailto:pandemicflu@dh.gsi.gov.uk), or alternatively, contact Ruth Hughes, HTA Regulation Manager: [ruth.hughes@hta.gov.uk](mailto:ruth.hughes@hta.gov.uk).

---

## Information for the research sector

### Procedure for allegations of misconduct in research

The UK Research Integrity Office (UKRIO) has published a model procedure for the investigation of allegations of misconduct in research. Further information can be found on the [UKRIO website](#). We advise all Designated Individuals overseeing research on human tissue to familiarise themselves with the procedure.

### Regulatory and governance advice service

The UK Clinical Research Collaboration (UKCRC) has established a UK-wide regulatory and governance (R&G) advice service which offers support to those involved in health research. The R&G advice service aims to give consistent and authoritative advice on a range of regulatory and governance issues. The HTA is part of a network that supports this service by providing advice and guidance in response to queries.

The service is jointly coordinated by the UKCRN R&G team and the Medical Research Council Regulatory Support Centre. More information is available on the [UKCRC website](#).

---

## Information for the organ and bone marrow transplants sectors

### Organ donations

From 1 April 2008 to 30 September 2008, 524 reports from Independent Assessors (IAs) were submitted to the HTA, 520 of which were approved. Two cases are currently awaiting more information before they can be adequately assessed, and two are currently with panels for decision. Since 1 April 2008, 16 reports have been referred to a panel of HTA members for a decision. More information for IAs can be found in our [IA bulletin](#).

### **Bone marrow donations**

From 1 April 2008 to 30 September 2008, 33 reports from Accredited Assessors (AAs) were submitted to the HTA, all of which have been approved. More information for AAs can be found in our [AA bulletin](#).

---

## Inspections update

Since the HTA began licensing in 2006, we have completed 639 phase one (desk-based) inspections and 180 phase two (site-visit) inspections across our five licensed sectors. Inspections are usually scheduled according to assessed risk; however they may also be scheduled randomly or on a reactive basis following receipt of information.

---

## Public Authority and report-back meetings

Thank you to everyone who attended our public Authority and report-back meetings on 18 September 2008 at the Wellcome Collection Conference Centre. If you would like to [read the papers from the meeting](#), please visit our website.

Seventy people attended the annual report-back meeting which provided an update on our work over the past year. People from two of the sectors we regulate gave presentations about their work and how the HTA's regulation has helped drive up standards. This event also saw the launch of our five summary inspection reports and the guide to our key messages.

[You can download all of the presentations from the event](#) from our website.

More information about the summary inspection reports and key messages guide is provided earlier in this e-newsletter.

---

## Recent media stories about human tissue

### **Summary inspection reports**

When the HTA launched its summary inspection reports we issued a [media release](#) which was covered in the British Medical Journal and BMA news.

---

### **Previous e-newsletters**

[Previous copies of the HTA's e-newsletter](#) are available in the publications section of the HTA website.

## Subscription to HTA e-newsletter

[New users can subscribe to the e-newsletter](#) on our website.

If you no longer wish to receive the e-newsletter, you can unsubscribe by clicking on the link at the bottom of this page.

---

- [www.hta.gov.uk](http://www.hta.gov.uk) |
- [Unsubscribe](#) |
- [Contact Us](#) |
- [Privacy policy](#)