

Summary of compliance 2008/09

Regulating the research sector

Working together to drive up standards

Contents

Introduction	page	3
What did we report last time?	page	3
What changes have there been to the profile of the research sector since 1 April 2008?	page	4
What did we find during the phase 2 site-visit inspections undertaken between 1 April 2008 and 31 March 2009?	page	5
What learning can be drawn from the enquiries we receive?	page	9
What joint working was there between the HTA and other research related bodies and organisations, between 1 April 2008 and 31 March 2009?	page	11
What next?	page	13
Appendix 1: List of establishments that received an HTA phase 2 site-visit inspection in 2008/09	page	14

Introduction

1. In September 2008, the HTA published a set of five summary inspection reports; one relating to each of our licensed sectors. The reports provided an overview of how the sectors complied with HTA licensing standards and summarised the key learning points from a range of information that we held about our licensed establishments. The research report covered the period 1 September 2006 to 31 March 2008. It is available on our website: www.hta.gov.uk/db/documents/HTA-inspection-research-v3.pdf.
2. The aim of this report is to provide an overview of the period 1 April 2008 to 31 March 2009 including:
 - any changes to the number and types of research establishments
 - an update on the sector's compliance with our standards
 - a summary of the regulatory action we took
 - learning from inspections
 - some case studies based on some of the advice and guidance we gave, and
 - how we worked with other research related bodies and organisations

What did we report last time?

3. During the period 1 September 2006 to 31 March 2008, the HTA received 236 applications from establishments in the research sector. Of these, 98 were for stand-alone establishments and 46 were for hubs that altogether had a total of 92 satellite sites attached. Following phase 1 desk-based inspections of the 236 applications, we imposed 118 conditions across 49 establishments.
4. We undertook 10 phase 2 site-visit inspections of research establishments. As a result, we imposed a total of 13 additional conditions across five establishments. We provided 73 individual items of advice and guidance, most of which related to our governance and quality systems standards (GQS); specifically, the efficacy of audit and traceability systems.

What changes have there been to the profile of the research sector since 1 April 2008?

5. The number and types of research establishments have not changed significantly. During 2008/09 we received 13 new licence applications, mostly for higher education establishments. These establishments had generally either not previously stored relevant material (otherwise referred to in this report as human tissue) for research, or had only stored it for a specific project that had gained approval by a NHS Research Ethics Committee (REC). This meant that they were exempt from licensing.
6. Encouragingly, in order to make human tissue more widely available for research, some establishments have begun proactively consolidating the storage and governance of their tissue. In a few cases, we contacted establishments that had multiple licences and worked with them to consolidate storage, with the aim of decreasing the number of licences they had. In total, 20 establishments informed us that they no longer needed an HTA licence; nine of these establishments had merged with, for example, other departments within the same establishment, or became satellites of other establishments.
7. As reflected in last year's report, most research establishments met at least the minimum level of compliance with HTA standards. Many demonstrated that they had good, and sometimes exemplary, systems and processes to support licensable activities. However, we know from the additional 13 licence applications and the phase 2 site-visit inspections we conducted in 2008/09, that there are still some establishments that have not fully implemented quality management systems. We also know that there is still some uncertainty among the research community about the difference between the requirements and remit of the HTA compared with ethical review.

What did we find during the phase 2 site-visit inspections undertaken between 1 April 2008 and 31 March 2009?

8. Our findings are encouraging; research establishments are gradually increasing their compliance with our licensing standards. During this period we undertook 15 phase 2 site-visit inspections (five more than during the period 1 September 2006 to 31 March 2008). Even with the increase in inspections, we imposed fewer conditions; a total of eight across the licences of six establishments. During 2008/09, we gave 87 items of advice and guidance to a total of 13 establishments.
9. The picture remains positive when we compare the advice and guidance we gave during 2008/09 with that given during the period 1 September 2006 to 31 March 2008. Other than against the GQS standards, during 2008/09 we gave relatively less advice and guidance related to all our licensing standards (Consent, Premises, facilities and equipment and Disposal).
10. We gave the same amount of advice and guidance during the first and second batch of inspections relating to the implementation of quality management systems. On one hand, the consistency in our findings is not surprising, as we know that quality management, and, in particular, standardisation and centralisation of processes, is a concept the sector has historically been unfamiliar with. On the other, it indicates that not all DIs have improved their systems and processes in line with the advice and guidance we gave in the last report.

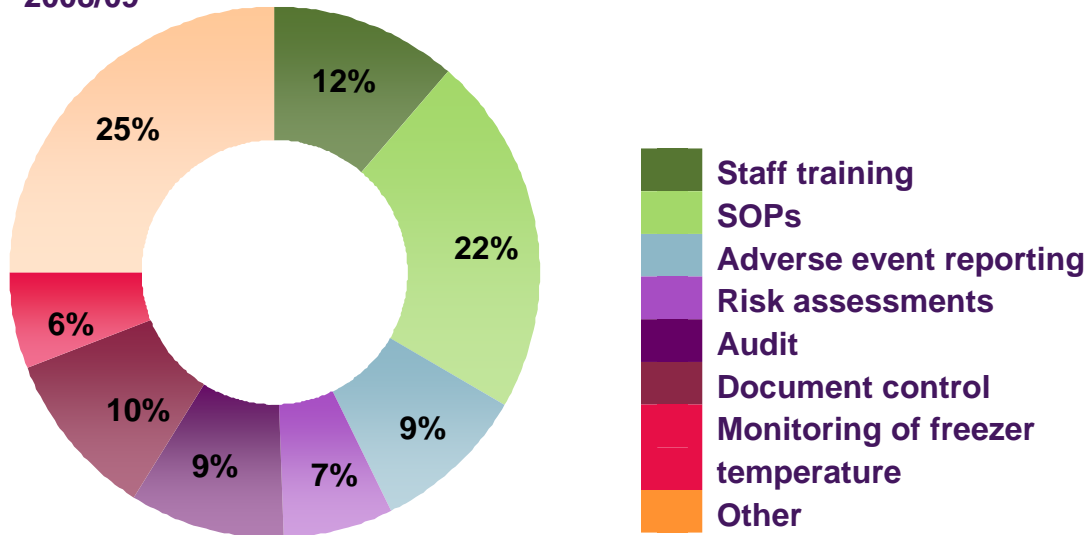
Learning point for Designated Individuals (DIs): conditions

Below, we detail some of the deficiencies that led to the conditions imposed after inspections in 2008/09. We advise that you consider whether these could be identified within your establishment and, if so, how they should be addressed:

- discrepancies in the records of stored relevant material. This may be, for example, where records show:
 - that relevant material is stored in one location but the records state another
 - a lack of clarity about the originating source
 - a lack of clarity about the use to which the relevant material can be put i.e. whether consent is specific or generic
- a lack of formal governance meetings and reporting between the DI and any Persons Designated (PDs)
- a lack of policies and standard operating procedures (SOPs) covering tissue acquisition through to disposal. Some establishments may have policies but it is important that, where applicable, these are supplemented by SOPs which provide a step-wise guide for staff handling relevant material
- a lack of formalised training on consent. This is particularly relevant to establishments that are obtaining relevant material from healthy volunteers
- a lack of risk assessments of the practices and processes taking place under the licence; for example, the process for receiving, logging and labelling relevant material
- a lack of suitable storage, for example storage areas that are not secure and do not have restricted access

11. Figure 1 illustrates a breakdown of the most common areas of advice and guidance. It demonstrates that more than a fifth are related to SOPs, which are an essential component of any quality management system.

Figure 1: Breakdown of advice and guidance given during 2008/09



12. A quarter of the advice and guidance we gave was categorised as 'other'. This included advice to DIs to:

- clearly label fridges and freezers so the tissue stored within it is easily traceable
- review Service Level Agreements (SLAs) and Material Transfer Agreements (MTAs) to ensure that when tissue is transferred to and from other establishments, responsibility for the integrity of the tissue is clear
- ensure that there are systems and processes in place to store and govern any tissue that will be stored once it is no longer being used in a REC-approved project

Learning point for DIs: SOPs

It is advisable that, if you have not done so already, you consider whether the following advice and guidance is relevant to your establishment:

- regularly review and amend all SOPs through a process of document control, so that changes to procedures can be audited
- ensure that all SOPs have authors, approvers, version numbers, a review history and a review date
- monitor staff adherence to SOPs
- communicate information about new SOPs and changes to existing SOPs to all relevant staff
- ensure that, if relevant material is distributed, an SOP covering the process from acceptance criteria for distribution, to transportation, is in place. The SOP should be supported by a risk assessment for the transportation
- put in place documented cleaning / decontamination procedures and a cleaning rota
- ensure that any SOPs on the storage of records includes how to make amendment to records, how long they should be retained and where applicable, when and how they should be destroyed
- ensure that the generic SOP on disposal requires the method, reason and date of disposal to be recorded

What learning can be drawn from the enquiries we receive?

13. During the period 1 April 2008 to 31 March 2009, we received a steady flow of enquiries from staff working in the research community. Enquiries are generally wide-ranging and do not always fall within the HTA's remit. However those that do, vary from enquiries about what storage records need to be maintained, to what arrangements need to be in place when human tissue is distributed.
14. This section of the report includes two case studies based on some of the most common enquiries.

Case study 1:

What do I need to do if I want to store tissue that I originally used for an ethically approved project?

Tissue that is used in a specific project which is approved by an NHS REC does not need to be stored on HTA-licensed premises. However, once the project approval expires, the tissue will need to be brought within the HTA licensing framework in order for it to be used in future, as yet unspecified, research projects.

If you have completed a project and your ethical approval has expired, you will need to do one of the following:

- transfer the tissue to HTA-licensed premises
- apply for an HTA licence at least three months in advance of the ethical approval expiry
- apply for extended or new ethical approval
- dispose of the tissue (this should be a last resort)

What records will I need to have in place if the tissue is going to be stored under an HTA licence?

You will need to keep the REC paperwork and a record of consent (if the tissue was not originally anonymised) stating that the tissue can be used in any future (not specific) research project.

You will also need to include the tissue in any centralised traceability system, and record the following information as a minimum:

- the type of tissue stored
- where it originated from (if known)
- where it is currently stored
- the researcher or group responsible for the tissue
- the use which it can be put to, including any restrictions
- any disposal requirements

Case study 2:

I want to undertake a multi-centre study. What do I need to do to ensure that I comply with the HT Act?

Licensing

Tissue for research can be obtained from a variety of collaborating establishments; although the research may only take place at one establishment. Generally, this arrangement is known as a multi-centre study. The vast majority of multi-centre studies will be approved by an NHS REC, so tissue used in the study will not need to be stored on HTA-licensed premises.

However, some tissue taken from the living may not be immediately identifiable as tissue that is suitable for a multi-centre study. Suitability may not be ascertained until the clinical diagnosis has been determined.

While the tissue is being stored by the establishment from which it was obtained, pending diagnosis, the tissue falls outside of the HTA's licensing remit. Once the diagnosis has been made, and where the tissue has been identified as meeting the research study's acceptance criteria, it must be stored only while it is pending transportation to the establishment at which the tissue will be stored for the research. Tissue not accepted for the study, that will be used for other non-specific research, must be stored on HTA-licensed premises.

Consent

The collaborating establishment must ensure that consent is obtained for the tissue to be used in a multi-centre study unless it is a certainty that it will be anonymous to the researcher and or research group and the study has gained NHS REC approval. Even though the above exemption to consent is legal, the HTA advises that, where practical, consent is sought.

Healthcare professionals seeking consent should consider whether it is appropriate to ask the participant whether they would be happy to give their generic consent for the use of their tissue in research, not just for the specific study. Obtaining generic approval avoids the need to obtain further consent.

For more information about obtaining consent for research, you can refer to the HTA code of practice on research, available on our website:

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>.

What joint working was there between the HTA and other research related bodies and organisations, between 1 April 2008 and 31 March 2009?

15. During this period, we produced a new code of practice on research. The code was developed in response to feedback from staff working at HTA-licensed establishments, as well as other key stakeholders. It was felt that a primary reference source for people working with human tissue would be useful. Many stakeholders had input into the drafting of the code, mainly through workshops, as well as responding to our consultation. We are very grateful for all the comments and suggestions we received.
16. As well as producing the code, following stakeholder consultation, we developed and implemented a continuous licensing system. Licences no longer have end dates, reducing the burden of licence administration and renewal for establishments.
17. We have provided information on a variety of research-related matters, such as revised guidance on the definition of relevant material, via our e-newsletters, which are available on our website:
www.hta.gov.uk/newsandevents/e-newsletter.cfm
18. We further developed our working relationship with a variety of stakeholders; working collaboratively with, among others, the Department of Health (DH), the National Stem Cell Network (NSCN), the National Research Ethics Service (NRES) and the National Cancer Research Institute (NCRI). Some of the outcomes of this joint working are as follows:
 - the implementation of a memorandum of understanding (MOU) with NRES
 - the production of a regulatory route map for stem cell research, which has been developed by the DH with the support of regulatory bodies and the Gene Therapy Advisory Committee (GTAC). The route map is intended to be a reference tool for those who wish to develop a programme of stem cell research and manufacture, ultimately leading to clinical application. This is available via our website:
www.hta.gov.uk/newsandevents/htanews.cfm/477-Regulatory-route-map-for-stem-cells.html. The aim is to produce a detailed, web-based 'UK Regulatory Route Map for Stem Cell Research and Manufacture' by the end of 2009

- information for DIs about the Research Integrity Office's (UKRIO) model procedure for the investigation of allegations of misconduct in research

19. At the end of 2008, the 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. 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. Opinion Leader carried out the evaluation between January and April 2009; 295 people took part via telephone and online interviews.

20. The results of the evaluation showed that 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. 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. The results of the review are available on our website:
www.hta.gov.uk/publications/evaluations.cfm.

21. The development of the new code and our proactive approach to joint working and information sharing, demonstrates our commitment to responding to enquiries, information requests, and feedback from the research sector. If you think that there are matters within our remit that we could consider in order to provide guidance or a policy decision on, you can email Christopher Birkett at christopher.birkett@hta.gov.uk.

What next?

22. Throughout the 2009/10 business year, the HTA plans to work with DIs, Licence Holders and Persons Designated from the research sector to help increase compliance with our governance and quality standards.
23. We also plan to run another stakeholder training event before April 2010. The event, which will be advertised via our e-newsletters and website, might also be supplemented by 'hot topics' in e-newsletters, which focus on the implementation of quality management systems.
24. We will continue to work collaboratively with organisations such as NRES, NCRI, NSCN and GTAC on any matters of mutual interest. We will also consider how best we can address the less positive findings of the external review. The aim will be to increase understanding amongst the research community of the requirements of the HT Act, how to comply with our licensing standards and the distinction between the role of the HTA and ethical review.
25. We will continue to respond to enquires from the sector and identify trends and themes; summarising learning points that can be shared.
26. We hope this report has been useful for you. If you have any suggestions for how we can improve the format and content of our reports, email christopher.birkett@hta.gov.uk.

Appendix 1: List of establishments that received an HTA phase 2 site-visit inspection in 2008/09

- University of Ulster (12064)
- Cambridge University Hospitals NHS Foundation Trust, Cambridge University Hospitals (12315)
- Guy's and St Thomas' NHS Foundation Trust, Specialist Dermatology Laboratories (12340)
- Cardiff University / Cardiff & Vale NHS Trust (12422)
- Department of Biochemistry, University of Oxford (12343)
- University of Northumbria at Newcastle (12495)
- United Bristol Healthcare Trust, Bristol Royal Infirmary (12152)
- Medical Research Council, Weatherall Institute of Molecular Medicine (12433)
- Cardiff University (12457)
- King's College London (12522)
- King's College London (12523)
- Wales Cancer Bank, Singleton Hospital site, Morriston Hospital site, Worthybush Hospital site (12107)
- Bangor University (12448)
- University of Oxford, Clinical Trial Service Unit & Epidemiological Studies Unit (12168)

Details of all licensed establishments are listed on the HTA website:
www.hta.gov.uk/licensing/licensed_establishments.cfm.

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