Site visit inspection report on compliance with HTA minimum standards

University of Bristol

HTA licensing number 12248

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

7-8 October 2015

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

University of Bristol (the establishment) was found to have met all HTA standards.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licenses against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

University of Bristol ('the establishment') has been licensed by the HTA, under the Human Tissue Act 2004 ('the HT Act'), since July 2007, for the storage of relevant material for use for a scheduled purpose. This licence covers the School of Medical Sciences (the hub) and the Langford House (the satellite).

The human tissue samples held at the hub are for education and training purposes. They are all existing holdings and include anonymised blocks and slides stored in teaching laboratories, and whole tissue potted specimens stored in another laboratory at the School of Medical Sciences. It is not recorded whether the blocks and slides were obtained from living or deceased donors; therefore all samples are assumed to be from deceased donors and considered to be held under the HTA licence.

The teaching laboratories are used to teach professional and undergraduate courses for dentists, medical and veterinary sciences. The majority of blocks and slides in the teaching laboratories are kept in locked storage cabinets and the establishment is in the process of cataloguing all the blocks and slides into an online database. The establishment also holds animal tissue slides for comparative histology teaching; however, human tissue blocks and slides are stored in separate boxes in the storage cabinets. The blocks and slides held in storage cabinets can be used for education and training. The University has plans to scan

and add the slides to the virtual microscope system at the University. No new samples are received for storage or released for research.

There are 119 student desk drawer spaces in the laboratory. Approximately 350 labelled human and animal tissue slides are kept in each desk drawer for undergraduate courses. There is no log of total number of slides kept in student desks and the slides are only replaced when a student brings it to the attention of the technicians that slides are not present (see advice item 3). The slides in the desk drawers are replaced from the collection of survey slides in the event of breaking or loss of slides. The survey slides are kept in a separate cupboard in the teaching laboratory.

Eleven potted pathology specimens that pre-date the HT Act are also used for teaching. Dedicated members of staff remove the specimens from the cupboard for teaching purposes. In addition, anatomical specimens may be loaned from University of Bristol's Anatomy licence 12135 under a documented loan agreement. A traceability record sheet for some of the specimens brought in from the anatomy licence is kept in the laboratory (see advice item 2).

The satellite site is located outside the city of Bristol and stores several thousand formalin fixed placentas in tubs from the Avon Longitudinal Study of Parents and Children (ALSPAC), for which project-specific research ethics committee (REC) approval has expired. These samples were collected as part of the longitudinal study carried out at University of Bristol. The samples are anonymised and stored in small tubs (one placenta) or large tubs (8-20 placentas) at room temperature (between 5 - 25 ^{o}C). The temperature in the storage area is monitored and a local member of staff manually records the temperature once each week. In the event of a temperature control breakdown, an alarm will sound locally and the automatic on-call alarm system calls the ALSPAC laboratory mobile at University of Bristol's licence at Oakfield House (12512). The establishment has contingency arrangements in the event of a temperature monitoring system failure.

Other samples from the same donors and their family members from the ALSPAC research project are stored at the premises of University of Bristol Oakfield House (licensing number 12512). The research group uses an electronic database to provide traceability of samples, including of repeat samples from the same donor, and to provide an anonymised link to clinical data (see advice item 1). Sample traceability is managed by a dedicated team of staff at the establishment, who update the electronic traceability records and conduct regular audits of stored samples.

Samples may be released on the basis of ALSPAC access policy, to researchers who apply to receive samples for use in research. Applications to receive samples are reviewed by the ALSPAC executive committee and the ALPSPAC Independent Scientific Advisory Board. The samples are released only after material transfer agreements are put in place and are transported through University-approved courier services.

The establishment disposes of human samples by incineration. Records of disposal are made, including the date, method and reason for disposal (see advice item 7).

This report describes the second site visit inspection of the establishment since it was granted a HTA licence in June 2007. This was a routine site visit inspection to assess whether the establishment is meeting the HTA's licensing standards. The site visit inspection included a visual inspection of the areas where relevant material is stored under the licence, a review of documentation and meetings with establishment staff.

An audit of traceability records was conducted. This audit included two forward and two reverse traceability checks for blocks and slides stored in the teaching laboratory, the potted pathology specimens, and one small and one large tub containing placentas. The audit revealed an anomaly in recording the number of survey slides on the database (see advice

item 3). No other inconsistencies were found in the storage locations or sample identifiers recorded on the electronic databases or paper records.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

At the time of writing this report Langford House was re-licensed as a satellite premises of the University of Bristol, Oakfield House licence (12512). The advice provided in this section still applies to the satellite premises and will be followed up during the next inspection of the licence 12512.

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ4	Although the research team maintains the database of the samples stored at Langford House, this procedure is not documented. The DI is advised to develop a documented procedure for the creation, amendment, retention and destruction of records. This SOP may include the details about, updating the database following addition of new sample to the database, recording release of research materials and disposal. This will help to ensure that records of sample traceability are complete, and may also facilitate audits of sample traceability.
2.	GQ5	At the time of inspection, it was noted that two lecturers are bringing anatomical specimens for undergraduate courses on loan from University of Bristol's anatomy licence. The log of some of the borrowed specimens is kept in the teaching laboratory. There is an inconsistent approach to record keeping in the teaching laboratory for anatomical specimens loaned from University of Bristol's anatomy licence. The DI is advised to ensure appropriate and up to date records are maintained for all teaching specimens on loan from other licences and establishments.
3.	GQ6	Currently, the establishment has no log of the total number of slides kept in student desk drawers. The HTA understands the practical difficulties in accounting for all the slides from 119 desks after each teaching session. The DI is advised to check the total number of slides at regular and reasonable intervals; for example, at the beginning and end of each term. It would be worth considering whether students could be involved in more frequent accountability checks. In addition, a complete traceability record should be kept of new survey slides issued to students and their disposal. The DI is also advised to ensure the number of survey slides in the cupboards is recorded in the database. This may also facilitate audits of sample traceability.
4.	GQ8	The DI should review the establishment's risk assessments to ensure that they include sufficient details of procedures and the associated risks. For Teaching laboratories, • Existing control measure #1 for sample labelling mentions "SOPs are in place to prevent mislabelling of samples". This point is not relevant as samples were received with labels already affixed, and are not being re-labelled currently; • Existing control measure #3 for sample labelling states that "Individuals hold records of each sample which contain their ID number and location, such that if tissue is moved it should be possible to identify its ID by its position even if it has lost its label." The number of slides in each student desk drawer is not recorded or

		audited. • The DI is advised to further elaborate the existing control measure #4 for sample labelling. The control measure should describe the process of recording of movement of samples and where these records will be kept. • Not all areas in which human tissue is kept have restricted access and the risks for access to the teaching laboratories should be assessed separately and documented. In relation to the Langford House risk assessments, the DI is advised to review and develop the risk assessments to include loss of traceability, failure of temperature control in storage facilities and accidental disposal of relevant material.
5.	PFE3	Where storage units are also used to store non-human tissues, the DI is advised to include details of the dedicated shelves or boxes used for the storage of human samples. This will help to ensure that human and non-human samples are segregated in order to address sensitivities that some donors may have around the storage of their samples with non-human tissues.
6.	PFE3	The DI is advised to schedule manual challenges of the storage temperature alarms at Langford House to ensure that they are operating as expected. This should include checks that the system notifies the University security desk as expected and that alarm notifications are responded to appropriately. These checks and any resulting actions should be documented.
7.	D2	The DI is advised to ensure that the date and method of disposal of slides from the teaching laboratory is recorded in line with regulatory requirements and these records are available for regular audits.

Concluding comments

This report outlines the second HTA site visit inspection of University of Bristol. There were a number of areas of good practice observed during the inspection. The DI and PDs maintain good oversight of the collections of human tissue stored under the HTA licence. The Research Governance Team helps the DI to carry out yearly internal audits of the human tissue samples stored under the licence. The Research Governance Team, Corporate Licence Holder contact and DIs of all licences held by University of Bristol are part of the Human Tissue Working Group (HTWG). HTWG serves as a good platform to share learning between DIs and improves the management of all licences held by the University.

The HTA has given advice to the Designated Individual with respect to documented procedures for management of traceability records, maintaining sample traceability, review of relevant risk assessments, establishing a manual challenge of alarm systems and maintaining appropriate disposal records.

Report sent to DI for factual accuracy: 28 October 2015

Report returned from DI: 10 November 2015

Final report issued: 15 November 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.