Site visit inspection report on compliance with HTA minimum standards

The School of Dentistry, Birmingham

HTA licensing number 12313

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**

28 April 2016

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.

The School of Dentistry, Birmingham (the establishment) was found to have met all HTA standards.

Since the date of the last inspection, the establishment has moved to new premises and, as part of the new building works, commissioned an external cryostore facility.

Particular examples of strengths and 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 licences 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

The School of Dentistry (the establishment) is part of the University of Birmingham and the clinical departments are run in conjunction with Birmingham Community Healthcare NHS Trust. Dental staff are employed either by the Trust or the University but hold honorary contracts for the other institution. Both clinical and non-clinical academic staff hold honorary NHS contracts.

The establishment has an established research programme and stores relevant material, principally teeth, but also soft tissue, saliva, plaque and blood samples, in two research tissue banks (RTB), which have both received ethics approval and are registered with the Health Research Authority. Relevant material, which is always from the living, is stored with appropriate consent and used for the scheduled purposes of research, and training and education.

Consent is taken by trained staff members or dental students, working to a defined standard operating procedure (SOP). Where teeth are to be donated following extraction in minor oral

surgery clinics, oral consent is taken and recorded in patient notes. A drop-down menu in the electronic patient record facilitates this.

Patient information, provided on visual display units in waiting areas and in printed leaflet form, as well as the consent SOP and provided as part of the consent taking discussion itself, clarifies that extracted teeth are donated anonymously and that subsequent withdrawal of consent is therefore impractical. Where consent has been obtained for use in research, clinical staff place donated teeth in a receptacle which is uplifted by research technical staff on a weekly basis. Teeth which are not suitable for use in teaching or research are disposed of at this point. Suitable teeth are cleaned and placed into storage boxes within a designated freezer. Linking an individual tooth to a donor becomes impossible immediately they are placed into the receptacle used for collection. Accordingly, all of the information provided to potential donors makes it clear that, when consent has been given for donation for extracted teeth, the practicalities mean it cannot be withdrawn after the teeth have been placed into the storage receptacle. This approach was discussed when the tissue bank application was reviewed by the relevant ethics committee and is reflected in the ethics approval given for the tissue bank.

In circumstances where soft tissue is donated following periodontal or oral surgery, or where blood or other samples are taken for use in specific projects, consent is obtained in writing and a copy of the completed consent form is retained. Samples are ‘pseudonymised’ (de-identified) so that researchers do not have access to donor-identifiable information. Swipe card access ensures that only a limited number of identified staff have access to research files stored securely in two areas of the hospital and the access to the database records containing patient identifiable information is also restricted.

Researchers have no access to any consent documentation but, if needed for some reason, the presence of valid consent can be verified by communication with the clinical trials coordinator.

Traceability of soft tissue, blood, saliva and plasma samples is maintained by the use of a unique hospital number for each parent sample. The sample database details what subsequent samples are derived from the parent sample and this, together with paper log books, records the location of each of the samples within the storage facility. This allows the clinical trials coordinator to identify relevant samples to staff should a donor wish to withdraw consent.

Storage of donated teeth takes place in a -20ºC freezer, frozen tissue samples are stored in one of two -80ºC freezers, the second acting as a contingency store, and paraffin embedded samples are stored within a cabinet, all located in a secure, restricted access biorepository.

On the date of the inspection, establishment staff were in the process of commissioning two liquid nitrogen storage tanks within a secure, external cryostorage facility and the samples stored in the -80ºC freezer will be moved to those tanks, with the freezers acting as contingency storage. As part of this procedure, all frozen temperature storage equipment will be connected to a web-based temperature monitoring system, with automated call-out when there is an out of temperature event. In the interim, freezer and room temperatures are being recorded daily by technical staff.

Disposal of samples is in accordance with a defined process, following university human tissue waste procedures, and is recorded within log books or databases as appropriate.

The establishment also has an archive collection of display specimens used for teaching of dental students. These had not yet been placed within display cabinets as they were still in storage following the move to the new building. Staff described the procedures used to catalogue the specimens, which had not changed since the last HTA inspection. These specimens were not reviewed as part of this inspection.

This was the second, routine, inspection of the establishment, the previous inspection having taken place in 2008. The establishment had recently moved premises and had been in-situ for approximately a month prior to the inspection date. Systems and processes were still relatively new but the HTA noted that many governance documents had been updated. Further review and updating of documentation is planned as the various elements of the new storage facility are commissioned.

The inspection comprised a visual inspection of the new premises, including the liquid nitrogen cryostore, the biorepository, and the oral surgery clinic where consent is taken, a review of governance and record documentation and interviews with key staff. The visit to the oral surgery clinic enabled staff to demonstrate the electronic patient record file system, which incorporates drop-down menus for the recording of consent

An audit of traceability was also carried out:

- Four sets of samples were located in the biorepository and the unique hospital numbers recorded. The storage locations were compared with that recorded in the freezer and sample log books and databases. The relevant consent forms or patient files with record of consent were retrieved and reviewed.
- One set of samples was selected from the clinical trials database, the relevant consent form reviewed and the samples located in store. Records relating to Material Transfer Agreements for transfer of three of the stored samples elsewhere were noted.

No discrepancies were found and the HTA noted the effective separation of systems used by staff accessing patient-identifiable information from those used by research and technical staff accessing samples in store.

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

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

No.	Standard	Advice
1.	GQ2	The HTA noted that various audits have been carried out, including a vertical audit of sample traceability and audits of the consent process, which included an observational audit of the consent procedure. The DI is advised to ensure that the schedule of audits in place for the coming year includes audits relating to the completion of consent documentation and the recording of oral consent in patient files. This should help the DI to assure himself that consent procedures remain robust, and identify any issues relating to accurate completion of consent documentation, particularly in relation to the new electronic patient record system.
2.	GQ7	The DI is advised to update risk assessments following the final commissioning of the new cryostore equipment and the embedding of other systems within the new building. These should cover storage, transportation, contingency arrangements and alarm warning systems following the relocation of the storage

		facilities. By updating risk assessments, staff can identify any changes to the risks resulting from the move to the new building and different infrastructure, which will inform further development of procedural and other governance documentation.
3.	PFE3	The DI is advised to put in place a schedule of periodic testing of the alarm system to be installed in the cryostore and biorepository. By doing so, the DI will help to minimise the risk of damage to stored samples in the event of equipment failure.
4.	PFE3	The DI is advised to update the contingency plan for storage failure following final commissioning of the cryostore and to ensure that this is circulated to staff involved in activities under the licence. By doing so, the DI will help to minimise the risk of damage to, or loss of, stored samples in the event of equipment or systems failure.
5.	D1	The DI is advised to review the wording of the SOP, “Receipt, storage and disposal of all human soft tissue specimens” to clarify that the reason and method for disposal are recorded where appropriate in sample logs and databases. The HTA noted that that staff do record this information, but that the SOP itself is not specific on these points.

Concluding comments

The HTA saw various examples of good practice during the inspection:

- Staff had put in a great deal of effort to update governance documentation following the move to new premises. Robust procedures are in place to continue the on-going reviewing and updating of the remaining governance documents.

- There is a close working relationship between academic and NHS staff involved in different areas of research projects which helps shared learning.

- Consent training appears to be robust, with all new staff and students receiving training on generic and research-specific consent, research ethics and the regulatory background. All staff involved in research must also complete MRC training on consent as part of Good Clinical Practice.

- The auditing of consent procedures at the establishment includes staff in clinical areas carrying out observational audits of those seeking consent. This has resulted in the development of a drop-down menu in the electronic patient file to prompt the recording of oral consent.

- Robust procedures have been put in place to ensure restricted access to donor-identifiable information and the security systems of the new building have been well considered to incorporate various levels of restriction of access. Access to databases and research-related records is also restricted to a defined staff group.

- As part of the commissioning of the external cryostore, the contingency storage arrangements will be more robust, minimising the risk of loss of valuable samples donated for research.

The HTA has given advice to the Designated Individual with respect to audits, risk assessment and some elements of governance documentation.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 9 May 2016

Report returned from DI: 9 May 2016

Final report issued: 10 May 2016

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.