Site visit inspection report on compliance with HTA licensing standards

Bristol Dental School and Hospital

HTA licensing number 12200

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**

6 April 2017

Summary of inspection findings

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

Bristol Dental School and Hospital (the establishment) was found to have met all HTA standards.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment
This report refers to activities carried out at Bristol Dental School and Hospital (the establishment). The establishment is licensed for the storage of relevant material for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The scheduled purpose in this case is 'Research in connection with disorders, or the functioning, of the human body'. The establishment has been licensed since 2007 and was last inspected in 2013. This inspection was the second routine site visit inspection.

The Designated Individual (DI) is the Clinical Research Manager at the establishment. The Corporate Licence Holder is University of Bristol, and the Corporate Licence Holder contact (CLHc) is the University's Pro Vice-Chancellor (Health). There are five people in the Person Designated (PD) role under the licence.

The establishment stores teeth and saliva collections in two Research Tissue Banks (RTB); the Tooth Tissue Bank and the Saliva Tissue Bank. Both RTBs have generic ethical approval obtained from Health Research Authority NHS Research Ethics Committees. In addition, there is a collection of human bones (primarily human skulls, used for education and training) and a collection of histological slides and teeth, which are 'existing holdings' and therefore are not subject to the consent requirements of the HT Act but are subject to the licensing requirements of the HT Act. Relevant material in both RTBs is obtained from living participants and is stored and used, with appropriate consent, for the scheduled purpose of: 'Research in connection with disorders, or the functioning, of the human body'.

Tooth Tissue Bank (TTB)
Teeth donated to the TTB are used for a number of projects investigating factors contributing to tooth discolouration and decay, and preventative products. Patients are recruited from the establishment, as well as three collaborating dental sites. Following a tooth extraction for clinical reasons, participants are asked if they would like to donate the extracted tooth to the RTB. Patients are provided with an opportunity to read the patient information sheet which details that teeth are donated anonymously and that withdrawal, following donation, is impractical (see Advice, item 1).

Consent is sought by trained clinicians and one copy of the consent form is kept with the patient notes, one is given to the patient and the PD retains a third copy.

Teeth are collected by the PD on a weekly basis. Batched teeth from the collaborating dental hospitals are also sent to the establishment on a regular basis. Following receipt of the teeth, the PD updates the TTB database, cleans the teeth and places them in a solution for storage. Collected teeth are pooled and stored in batches, which makes it impossible to link the donor to the tooth once placed in the storage receptacle.

When a researcher wants to use the teeth, a request is submitted to the PD. If the project is internal (for example, the research is to be undertaken by a student), the proposal will be peer-reviewed by an internal and an external reviewer. Companies often request teeth for projects and their proposals are reviewed by Bristol Ethics Committee before teeth are released. The PD maintains and updates a log of the teeth, noting whether the teeth have been sectioned, released for a project or disposed of. Following completion of a project, the researcher must either confirm disposal, or return the teeth to the TTB for disposal.

Saliva Tissue Bank

Saliva donated to the Saliva Tissue Bank is used to investigate the methods through which oral healthcare products interact with tooth enamel. Saliva is obtained from staff and students at the establishment. Trained staff seek consent and are observed regularly (see Advice, item 2). At the time of giving consent, the volunteer can consent to providing multiple samples. Researchers wishing to use saliva must provide a detailed proposal for the study to the PD. The proposal is peer reviewed by two reviewers before the study can be begin.

Saliva is collected and pooled in a batch, which is used for ongoing studies. When a batch has been exhausted volunteers are re-recruited, and where necessary, repeat consent is sought.

A log of samples is kept on the freezer door and researchers must complete the log when removing samples. The Saliva Tissue Bank manager maintains oversight of this log.

Samples are stored at -20°C; however, they are repeatedly thawed and refrozen, and may be stored at higher temperatures (see Advice, item 7).

Skull collection

A collection of skulls is held under the licence for teaching purposes. The bones are catalogued and colour-coded to prevent mix up when in use. A log is maintained of all specimens, including when they are moved to other areas within the establishment for teaching.

The inspection

The inspection comprised: a roundtable discussion with members of staff working under the licence; a visual inspection of the areas where human tissue is stored under the licence; interviews with the Tooth Tissue Bank manager (PD), the Saliva Bank manager (PD), a Consultant Senior Teaching Fellow (PD), the University Head of Research Governance and the DI, and; a review of governance documentation.

In addition, traceability audits were carried out for six samples stored at room temperature, 18 collections and three samples stored at -20°C. Samples were identified from their storage locations and traced to relevant documents. No anomalies were identified; however, in one case, the consent form had not been completed as per the protocol (see Advice, item 4).

Inspection findings

The HTA found the Licence Holder, the Designated Individual and the premises 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.	C1(d)	Consent for tooth donations is sought following tooth extraction for clinical reasons. Donors are provided with time to consider the patient information sheet, before consent is sought. The DI is advised to provide information in the waiting room. This will allow additional time for potential donors to consider participating in the studies, as well as potentially increasing the number of donations.
2.	C2(c)	Staff involved in seeking consent for the Saliva Tissue Bank are regularly observed when seeking consent to assess competency, however this procedure is not formally documented. The DI is advised to record and document this procedure.
3.	GQ1(d)	The DI formally meets with all PDs in advance of the yearly audits. The DI is advised to hold a follow-up meeting, to discuss the results of the audit, including CAPAs and any outstanding actions. The meetings could also be used as an opportunity to discuss adverse incidents and any updates from the HTA.
4.	GQ2(a)	Audits are carried out by PDs on a yearly basis and PDs audit a different collection to their own. A further audit is performed by the Head of Research Governance and a DI from another licence at the University of Bristol on a biannual basis. Both audits include vertical audits of sample traceability. The DI is advised to include an audit of the completion of consent documentation in the schedule of audits. This will provide additional assurance to the DI that the consent process remains robust, and will identify areas where the consent documents are not accurately completed.
5.	GQ5(b)	A robust incident reporting system is in place; however, the SOP and the adverse event report categories have not been updated as incidents have been reported. For example, the most recent adverse events have been similar in nature but the current format of the adverse incident reporting form means that they can only be categorised as ‘other’.

		As experience of incidents evolves, the adverse incident reporting form should be reviewed and updated accordingly to allow incidents to be categorised and captured appropriately.
6.	GQ6(b)	Risk assessments should be reviewed every 1-3 years, as well as following an incident, to ensure actions to mitigate the risks are updated appropriately.
7.	PFE2(c)	Saliva samples are held in a -20°C freezer, and are assessed for inadvertent thawing on an ad hoc basis. Sample quality is not dependent on storage at this temperature but the DI is advised to install a temperature probe to provide accurate readings. Monitoring of these temperatures will provide an assurance to the DI that samples are being consistently stored at this temperature.

Concluding comments

During the inspection, areas of good practice were noted, including a good working relationship between the DI, PDs and the Head of Research Governance. All staff demonstrated a good understanding of the requirements of the HT Act and the HTA's Codes of Practice. The Human Tissue Working Group encourages communication across the five licences held by the University of Bristol. The tracking system in place for the traceability of skulls and bones used for teaching includes a robust colour coding system which has allowed for multiple teaching sets to be used at once and mitigates the risk of bones being inadvertently mixed up.

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

Report sent to DI for factual accuracy: 3 May 2017

Report returned from DI: 10 May 2017

Final report issued: 10 May 2017

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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

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.