Site visit inspection report on compliance with HTA licensing standards
Inspection date: **2-3 December 2019**

South West Dementia Brain Bank, University of Bristol

HTA licensing number 12273

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
South West Dementia Brain Bank, University of Bristol	Licensed	Not licensed

Summary of inspection findings

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

Although the HTA found that South West Dementia Brain Bank, University of Bristol (the 'establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for Governance and Quality systems.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfall identified during the inspection.

Compliance with HTA standards

Minor Shortfall

Standard	**Inspection findings**	**Level of shortfall**
GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	All consent forms (along with other paperwork, such as neuropathology reports, donor clinical summaries and donor medical records) are stored in a locked room. There are no provisions for back-up of these records.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

DI and CLH suitability

The HTA found the Designated Individual (DI) and the Corporate Licence Holder (CLH) to be suitable in accordance with the requirements of the legislation.

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The internal audit programme consists of an annual audit, against all relevant HTA standards, by the Research Governance Team. As the Brain Bank Team also performs *ad hoc* stock checks and procedural audits, the DI is advised to consider adding these audits to the schedule.
2.	GQ3(b)	The induction and competence training programme has been formalised into a draft matrix indicating trainees' progress for each task. The DI is advised to implement this programme as soon as possible for new and existing staff.
3.	GQ6(a)	Nominated staff use their own vehicles for the collection and return of brain tissue to the establishment. The DI is advised to consider expanding the transport risk assessment to include preventative measures in the event of breakdown or accident.
4.	PFE1(c)	The DI is advised to consider incorporating periodic decontamination of the -80ºC and -150ºC freezers into the documented cleaning procedure and cleaning schedule.
5.	PFE2(c)	The DI is advised to consider introducing temperature monitoring for the storage rooms which maintain formalin-fixed brain tissue and formalin-fixed paraffin wax-embedded blocks and sections at ambient temperature. Excessive or prolonged raised temperatures in these rooms may lead to sample degradation.

6.	PFE2(c)	The DI is advised to consider initiating a programme by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs.
7.	PFE2(d)	There are detailed, documented contingency plans for storage under other HTA licences within the University. The DI is advised to consider including a similar level of detail in the local plans for the use of alternative freezers to ensure that all members of staff can follow such plans swiftly and effectively.

Background

The South West Dementia Brain Bank, University of Bristol (the establishment) has been licensed by the HTA since September 2007. This was the second site visit inspection of the establishment; the last inspection took place in May 2009.

The establishment is part of Bristol Medical School within the University of Bristol. It is one of 10 Brain Banks in the UK, all of which are part of the Medical Research Council (MRC) UK Brain Banks Network. The establishment contains an NHS Research Ethics Committee (REC)-approved Research Tissue Bank (RTB) which contains formalin-fixed brain tissue, fresh-frozen brain slices and brain regions, formalin-fixed paraffin wax-embedded blocks and sections of brain tissue, cerebrospinal fluid and whole blood (117,600 samples). The brains are from deceased donors who have had a diagnosis of dementia (or other neurological condition) and from donors with no known neurological disease. The establishment also contains 34 studies involving stored samples from living and deceased donors which, at the time of the inspection, had existing project-specific REC approval. The storage of these samples (tissue, body fluids, swabs and whole blood) is exempted from HTA licensing.

Trained Brain Bank staff seek witnessed consent from the donor or from a person in a qualifying relationship to the donor. The establishment has agreements in place with mortuaries used for removal of the brain and spinal cord.

Requests for samples from the RTB are reviewed by the ‘Tissue Request Access Committee’. Once approval is given, a standard material transfer agreement is put in place by the DI or University Research Governance Team to cover sample transfer.

Since the previous inspection, the following changes have been made to the licence arrangements: the current DI was approved in January 2018 and the current CLH contact was registered with the HTA in March 2017.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

Standard C1(c) was not applicable to the inspection. All remaining 46 licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to licensed activities; meeting minutes; audits; staff training records; reported incidents; risk assessments; temperature monitoring of the freezer storage units; contracts for servicing of equipment and records of servicing; and agreements (mortuary agreements, material transfer agreements).

Visual inspection

The inspection included a visual inspection of the areas for sample receipt and release as well as the storage areas (-80ºC and -150ºC freezers, and ambient temperature storage areas).

Audit of records

Traceability audits were performed on brain tissue from three separate brain donors. The donors were selected at random from the electronic tissue register. All formalin-fixed brain tissue, fresh-frozen tissue, formalin-fixed paraffin wax-embedded blocks and sections of brain tissue were identified and located for each donor (101 samples in total). The consent form, labelling details, date of receipt and storage location details were compared to the electronic records. There were no discrepancies noted.

Meetings with establishment staff

Roundtable discussions were held with relevant staff working under the licence covering: the management of audits; incidents and risk assessments; governance meetings and training; standard operating procedures (SOPs); document control; contingency arrangements; agreements; distribution; and disposal. Further discussions were held with staff involved in seeking consent, and with the Persons Designated. Individual interviews were held separately with the DI and the CLH contact.

Report sent to DI for factual accuracy: 2 January 2020

Report returned from DI: 9 January 2020

Final report issued: 7 February 2020

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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 routine site visit inspection.

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