Site visit inspection report on compliance with HTA licensing standards

University of Sussex

HTA licensing number 12119

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**

31 May 2018

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.

Although the HTA found that the University of Sussex (the establishment) had met the majority of the HTA's standards, one minor shortfall was found in relation to Consent.

The DI has been given advice on a range of issues and 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 licensable activities carried out at the University of Sussex (the establishment). The establishment is licensed for the storage of relevant material that has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use for the scheduled purpose of 'research in connection with disorders, or functioning, of the human body'. The establishment has been licensed since September 2007 and this was the second routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The establishment stores relevant material under this licence in three collections each with a nominated Persons Designated (PD). The genome project collection is stored in the Genome Damage and Stability Centre (GDSC), the psychology collection is stored in the Pevensey Building and the biochemistry collection is stored in the John Maynard Smith Building.

There are overarching governance documents that cover all main activities being carried out under the licence. There is also a centralised database to facilitate the traceability of material. Many of the projects have approval from a recognised research ethics committee (REC) and are exempt from the licensing requirements of the Act, however the establishment adopts a harmonised approach to governance and sample management.

<u>The genome project collection</u>

The genome project collection stores approximately 1000 skin biopsies taken from the living. Material is held primarily for diagnostic purposes; however, surplus material is stored for research. Consent is obtained by clinicians (consent seekers) at a number of hospitals around the UK and there are service level agreements (SLAs) with consent seekers that confirm consent procedures comply with the HT Act and the HTA's Codes of Practice. The consent forms lack clarity and there is limited information about the activities for which consent is being obtained. There is no information given about the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of (see shortfall against standard C1(d)). Fresh biopsies are sent to the establishment using tracked couriers. Upon arrival samples are processed and given a unique accession number and recorded on an electronic database. Samples are stored in liquid nitrogen dewars in a secured building (see *Advice*, item 3). There are automated alarms that are triggered by deviations from the set acceptable temperature ranges which alert relevant members of staff by phone, 24 hours-a-day. The alarm system is tested during annual servicing.

<u>Psychology collection</u>

Samples held in this collection include buccal swabs and urine samples. Material is obtained from the living, from healthy volunteers and NHS patients. Personal investigators (PIs) are responsible for seeking consent and are fully trained in the requirements of the HT Act and

the HTA's Codes of Practice. Samples are either taken at the establishment or are sent to the establishment. Upon arrival, samples are allocated a unique number and logged on the database (see *Advice*, item 2). Samples are stored in a -20°C freezer until processing. There is an automated alarm fitted on the freezer that is triggered by deviations from the set acceptable temperature ranges which alert relevant members of staff by phone, 24 hours-a-day; however, the temperature is not regularly monitored. At the time of the inspection the establishment were in the process of setting up a new freezer and daily temperature monitoring will be possible (see *Advice*, item 4). PIs apply for sample access via an internal application system. The project risk is assessed and approval is provided by a University ethics committee. Some of the projects also have approvals from recognised RECs.

Biochemistry collection

Many of the samples held in the biochemistry collection have approval from a recognised REC or have been sourced from REC-approved tissue banks. Material that is relevant includes 20 plastinated brain sections which are used for teaching purposes. The specimens are imported from the USA and are stored in a locked cabinet in a secure office area. A dedicated technician is responsible for signing the specimens in and out during student practicals, and, both paper and electronic records are kept for traceability.

Description of inspection activities undertaken

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the DI, previous communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and roundtable discussions with staff involved in each of the collections. The inspection also included a visual inspection of the GDSC, the Pevensey Building and the John Maynard Smith Building. All collections were covered in the following audits:

- Four samples from records to consent to sample storage.
- Five samples from storage to records to consent.

All audited samples were fully traceable.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
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		
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.	Consent forms used for the collection of material in the genome project lack detail. There is limited information about the activities for which consent is being obtained. There is no information given about the types of research that may be involved, any wider implications and the circumstances under which the tissue will be disposed of.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The establishment has overarching SOPs for obtaining consent and the collection of material. The DI is advised to finalise and ratify the SOP related to the collection of buccal swabs and urine samples for the psychology collection.
2.	T1(a)	Samples in the psychology collection are assigned a code that incorporates the PIs initials and a numerical code. The DI is advised to strengthen this coding to include a date which will help mitigate potential duplication in the future (for example if a new PI with the same initials was to join the team).
3.	PFE1(b)	The liquid nitrogen dewars that store relevant material are situated in an unsecured room in the GDSC. The DI is advised to secure this room such that only authorised and trained personal have access.
4.	PFE2(c)	Temperatures of all freezers should be assessed frequently to identify any trends that may herald impending equipment failure.
8.	PFE2(c)	All relevant material is stored in freezers that have external alarm and call-out systems. The DI is advised to establish a system of regular manual challenge of the alarm systems to ensure that when temperature deviations are detected the system operates successfully.

Concluding comments

This report outlines the second routine inspection of the establishment. A number of strengths and areas of good practice were observed during the inspection, including:

- There is a harmonised approach to governance and sample management of relevant material held under the HTA licence and REC approvals from recognised RECs.

- Many of the SOPs that cover licensable activities have flowcharts to visually explain procedures. They are easy to understand and provide quick points of reference to staff working under the licence.

- The University holds multiple HTA licences and there are joint governance meetings with DIs on the other licences providing opportunities for shared learning.

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.

Although the HTA found that the University of Sussex (the establishment) had met the majority of the HTA's standards, one minor shortfall was found in relation to Consent standard.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls 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.

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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 18 June 2018

Report returned from DI: 02 July 2018

Final report issued: 05 July 2018

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 21 November 2018

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.