Site visit inspection report on compliance with HTA licensing standards

The Christie

HTA licensing number 30004

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**

14 & 15 May 2019

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 Christie had met the majority of the HTA's standards, eight minor shortfalls were found against a range of standards across three of the four main standards groups.

The DI has also been given advice on a range of issues.

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 by The Christie ('the establishment' and 'hub site') in Manchester. The licence includes the hub site - which is made up of the The Christie NHS Foundation Trust and The Paterson Building - and the associated satellite sites, which are the Oglesby Cancer Research Building (OCRB) at the Manchester Cancer Research Centre (MCRC) and the CRUK Manchester Institute at the Alderley Park site.

The Designated Individual (DI) is the MCRC Biobank Business Manager based at the hub site, in the Research Division. The Corporate Licence Holder (CLH) is The Christie NHS Foundation Trust and the Corporate Licence Holder contact (CLHc) is the Director of Nursing & Quality.

In June 2007, the establishment was granted a licence in the HTA's research sector for the 'storage of relevant material for use for a scheduled purpose', which in this case is, 'Research in connection with disorders, or the functioning, of the human body'. There have been several changes to the licence since it was granted; these include changes of both the DI and CLHc, changes of the Persons Designated (PDs) and changes to the licensed premises. The DI and PDs form the establishment's 'Human Tissue Governance Team' and are responsible for the overall governance of the storage and use of human tissue samples under the HTA licence.

Under the licence, the establishment stores human tissue samples which have either been imported, obtained on site or are from historical projects. As well as storing tissue under the licence, the establishment also stores tissue for use in projects which have current ethical approvals from recognised research ethics committees (RECs), thereby exempting the storage of these samples from the licensing requirements of the Human Tissue Act 2004 ('HT Act'). The Human Tissue Governance team maintains oversight of all of the tissue stored, which includes the tracking of samples, projects and ethical approvals.

The MCRC biobank has recognised REC approval to function as a research tissue bank (RTB). Both internal and external groups receive material from the RTB for use in research projects. The RTB stores samples from both cancer patients and healthy volunteers. Consent is obtained by biobank technicians who have received training in the requirements of the HT Act and have been assessed for their competency to seek consent.

A number of different tissue types are stored in the RTB and by the research groups. These include frozen tissues, formalin fixed and paraffin embedded (FFPE) tissue blocks and slides,

blood and urine samples. The biobank also includes samples collected from the diagnostic archive of the Christie NHS Foundation Trust Hospital and partner Trusts.

The establishment has different storage conditions across all of the sites. These include several -80ºC freezers, liquid nitrogen (LN2) tanks, room temperature storage and +4ºC fridges. Most of the storage locations are monitored using external calibrated probes, linked to an external alarm system which contacts members of the biobank team if temperatures deviate from expected temperature ranges. All buildings have swipe card access and entrances to the individual laboratories are further secured, granting access to staff only. Some storage areas have additional padlocks on the doors, and room temperature samples are either stored in locked storage or in a shared facility (see *shortfall PFE1 (b*)).

Description of inspection activities undertaken

The inspection was the third routine inspection of the establishment and consisted of a visual inspection, interviews with individual staff, traceability audits, a document review and a roundtable discussion with establishment staff.

At the time of the inspection, human tissue was being stored for several projects as well as in the RTB. Traceability audits were completed on the majority of the projects and selected tissue from the biobank. There were no discrepancies for any of the tissue stored within the biobank; however, there were some discrepancies for some of the research projects (see *shortfall T1(c))*.

Samples were selected at random from -80ºC freezers, room temperature storage, liquid nitrogen storage and a +4ºC fridge. Where possible, labels on the samples were noted and checked against the electronic records, copies of the project consent forms were then reviewed.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Whilst there is a documented schedule of audits, during recent years this has not been followed. Also, for the research groups, audit activities are limited in quality and frequency. See *Advice,* item 3.	**Minor**
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.	There is currently no system for record amendment.	**Minor**
b) There are provisions for back-up / recovery in the event of loss of records.	A number of the research groups are using paper records which are not backed up and cannot be recovered in the event of a loss.	**Minor**

Traceability

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
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.	The following issues were identified when completing the traceability audits for the research groups; • During some audits, the labels were either difficult to read or had peeled off. • There were inconsistencies between the key information that was recorded on storage tubes and the databases; for example, the database contained 'week number' but this was not on the tubes. • Some tissue samples were not in the correct locations. See *Advice,* items 7 and 8.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	Whilst assessments have been carried out, some storage locations are within a room that is not air conditioned and gets extremely warm. Although portable fans have been purchased and deployed, there is an ongoing risk to the optimal operation of the freezers, posing a threat to the integrity of the tissue being stored.	**Minor**

b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.	Some of the tissue samples stored at room temperature are not in a secure location, which means that they can be accessed by staff not trained or authorised to work with human tissue under the Human Tissue Act.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	Not all of the storage conditions are being monitored, specifically in the LN2 tanks.	**Minor**
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.	The following issues were identified during the visual inspection: • Not all storage equipment was on a maintenance or servicing contract; they were also not maintained by staff. • Some freezers were heavily frosted, which could impair their correct functioning.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1 (e)	The DI is advised to ensure that, if there is a language translation service for those giving consent, that all staff are aware of this when seeking consent. If, however, there is no translation service for those giving consent, the DI is advised to ensure that documentation reflects this.
2.	C2 (a)	The consent presentation seen by the inspection team would benefit all staff as part of the current training procedure. The DI is advised to consider using all of the materials that have been developed in-house, offering them to all staff when providing training.
3.	GQ2 (a)	Audits should include but not be limited to location audits, database audits and consent form audits. To assist with audits, smaller 'spot checks' could be completed by the research groups to increase the frequency of traceability audits and staff awareness of tissue in storage.
4.	GQ2 (b)	The DI is advised to add timeframes to the follow-up actions for the biobank audits as these should allow more effective monitoring of actions and progress.
5.	GQ3 (a)	The DI is advised to ensure that where staff are provided with HTA training, that this is maintained and kept up-to-date, in accordance with any agreed procedures or arrangements. The DI is also advised to ensure that where there are inconsistencies with refresher timeframes and the type of training required, that this is agreed and resolved with all staff working under the licence. Any agreements for refresher timeframes and training requirements should be communicated with staff so that they are aware of their responsibilities and requirements for HTA training.
6.	T1(a)	Some samples are sub-aliquoted into multiple vials, to give several identical samples. Although the number of vials and the individual aliquot locations are recorded to provide traceability for each of the samples, the same identifier is used for labelling purposes. The DI is advised to consider assigning a unique code to every specimen to minimise further the risks to a loss of traceability.
7.	T1 (c)	To facilitate traceability, the DI is advised to ensure that where boxes are used for tissue storage, they are labelled with the correct box orientation.
8.	T1 (c)	During one of the HTA's audits, it was found that there were a large number of tissue samples stored together in a bag. The DI is advised to review this practice as it may pose an unacceptable risk to the tissue thawing when undertaking audits.

9.	T2 (b)	The DI is advised to ensure that staff are recording the reason for disposal on the disposal form. In cases where a sample has been used up, this should be noted as the this supports full traceability.
10.	PFE1 (c)	Whilst there is a documented cleaning procedure, the DI is advised to ensure that staff are following this procedure for all storage locations and that any cleaning is recorded.
11.	PFE2 (c)	The DI is advised to ensure that staff are aware of the minimum and maximum temperature ranges of all storage locations.
12.	PFE2 (c)	To improve staff awareness, the DI is advised to add labels or signs to the storage locations to indicate where human tissue is being stored.
13.	PFE2 (c)	The DI is advised to formalise a procedure for testing alarms regularly.
14.	PFE3 (a)	The DI is advised to monitor and review temperatures for trends as this may allow the DI to indentify any potential storage equipment problems and action them before they occur.

Concluding comments

This report outlines the second routine inspection of the establishment.

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

Although the HTA found that The Christie (the establishment) had met the majority of the HTA's standards, eight minor shortfalls were found against a range of standards across the three of the four main standards groups.

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: 03 June 2019

Report returned from DI: 26 June 2019

Final report issued: 02 July 2019

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.