Site visit inspection report on compliance with HTA licensing standards

LifeArc

HTA licensing number 12634

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**

4 July 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.

Although the HTA found that LifeArc had met the majority of the HTA's standards, two shortfalls were found, relating to documentation and risk assessments.

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 LifeArc, formally MRC Technology, (the establishment), an independent life science charity which aims to improve patient outcomes. The establishment is licensed for the storage of relevant material which has come from a human body for use in a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples will be 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 2015 and this was the first routine site visit inspection. In the time since the licence was granted the establishment has not stored relevant material for use in a scheduled purpose.

The establishment will acquire human samples from a range of commercial and non-commercial suppliers within England and may also obtain samples from third parties in Scotland. The Designated Individual (DI) maintains oversight of all projects undertaken at the establishment, and any using human samples are flagged to him, and to both Persons Designated (PD) working under the licence. A PD will authorise a request for human samples to be sent to the establishment before an order is placed. The approval process includes completion of a request form which includes a check of relevant documentation, approval by an internal ethics committee and a check to ensure appropriate consent has been sought in accordance with the regulatory requirements (see Advice, item 1). The establishment anticipates that the majority of samples received will be from deceased donors.

The establishment has identified a -80°C freezer and a rack within a liquid nitrogen tank where relevant material will be stored (see Advice, items 11 and 12). The freezer is located in a secure laboratory area and is linked to an automated remote call out system which notifies relevant staff of temperature deviations outside of the accepted ranges (see Advice, item 13). An alarm will also sound locally. The liquid nitrogen tank is stored in a dedicated, secure room and is monitored. Liquid nitrogen top up is managed by LifeArc-employed staff in the estates department.

Upon receipt by the establishment, all samples will be assigned a unique identifier and will be labelled with an eye-readable label and a unique barcode. An electronic tracking system, Procuro, is currently being used to track other samples (e.g. lentivirus) in the establishment and will be used to track receipt, storage, use and disposal of human samples (see Advice, item 6).

Description of inspection activities undertaken

The inspection consisted of a roundtable discussion with establishment staff, a visual inspection of areas where samples will be stored, documentation review and interviews with the Director of Drug Discovery (DI), the Head of Site Services (Corporate Licence Holder contact), the Lab Manager (PD), a Team Leader (PD), and the Drug Discovery Manager.

The establishment plans to commence storing relevant material in six months. The shortfalls identified below therefore need to be completed to the HTA's satisfaction before this takes place. The HTA also expect all pieces of advice to be addressed before the storage of relevant material commences.

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
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.	Since the licence application visit the scope of material the establishment expects to receive has expanded. The documents in place are not sufficiently detailed to describe the planned activities. *See Advice, item 2*	**Minor**
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.	While a number of risk assessments are in place, they do not adequately address the risks described. For example, the risk assessment related to loss of traceability describes the risk of mislabelling a sample but does not adequately describe the process through which this can be mitigated. In the coming months the establishment intends to begin the storage of relevant material. The risks associated with receiving samples, for example, receiving specimens without appropriate consent documentation, or transport of samples to the establishment have not been documented. *See Advice, item 7*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	Staff at the establishment will not be seeking consent, however the DI is advised to assure himself that appropriate consent has been sought and should consider requesting blank versions of the consent forms and patient information sheets provided to participants. The DI may wish to consider revising the 'Human Tissue Acquisition Form' to clarify that consent is required to use human samples for research purposes.
2.	GQ1(a)	While the LifeArc Handbook has recently been updated, a new system for recording sample traceability is in the process of being implemented, and this is not described in the handbook. In addition, there is not sufficient information regarding the consent requirements under the HT Act; the process for collecting samples; transporting of samples; or cleaning and decontamination procedures. The handbook should be revised to ensure it provides sufficient detail to appropriately describe the activities being undertaken. The handbook should be reviewed with reference the latest version of the HTA's Codes of Practice and standards. The DI should ensure that documents are version controlled and updated on a regular basis, or following a change in procedure.
3.	GQ1(d)	Staff meet on an ad hoc basis, however there is no formalised meeting where licensable activities can be discussed. The DI is advised to add a standing agenda item in an appropriate meeting where staff working under the licence can discuss licensable activities, including incidents or audits and follow-up

		actions. These meetings should be documented and minutes circulated to relevant staff.
4.	GQ2(a)	Audits are currently undertaken at the establishment, however licensable activities are not currently included. The DI is advised to create a schedule of audits to demonstrate compliance against the HTA standards. Vertical audits of records and specimens should allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. Audits should be carried out on a periodic basis, or following a change in process. Shortly after receiving the first batch of samples the DI is advised to conduct an audit of all processes and procedures related to the samples. This will provide assurance that the systems in place are working as expected.
5.	GQ2(b)	The DI is advised that audit findings and corrective and preventative actions should be recorded, and should include timeframes for completion. The DI may wish to develop a form to record audits to ensure audits are consistently captured and followed-up.
6.	GQ3(a)	While both PDs working under the licence have attended a workshop held by the MRC, other staff who will be working under the licence have not undertaken training specific to the Human Tissue Act. The DI is advised to continue with the plan to ensure all staff working under the licence undertake the online module provided by the MRC, which was developed with input from the HTA. In addition, the DI should consider introducing a training programme for staff working under the licence which includes information on the HT Act and the HTA's Codes of Practice, the labelling system for specimens and the appropriate steps to take in the event of an adverse incident related to human samples. The DI may wish to distribute the package to all staff working in the establishment to raise awareness of the activities under the licence.
7.	GQ6(a)	While risk assessments are in place, the DI is advised to ensure that the full range of risks relating to premises, practices and procedures are covered, including: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • sample mix-up; • transport of specimens to and from the establishment • missing or incorrect documentation; • security arrangements; • abnormalities in storage temperature readings; • incorrect disposal.

8.	GQ6(b)	Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident. By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.
9.	T1(d)	The DI is advised to implement a system which ensures sample traceability is maintained during transport. For example, requesting an inventory from the establishment sending the samples, and sending confirmation upon receipt of the samples.
10.	T2(b)	The DI is advised to ensure the reason and method of disposal is recorded. This will help to ensure that staff are aware of the requirements to meet the HTA licensing standards. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.
11.	PFE2(b)	The establishment stores a range of biological material. To avoid the risk of sample confusion, and to ensure that human tissue samples are handled in line with the regulatory requirements under the HT Act, the DI should assure himself that all freezers and containers holding human tissue are labelled appropriately.
12.	PFE2(c)	The DI is advised to ensure alarms on freezers are regularly challenged to ensure they are operating as expected. This test should include testing the remote call out system to ensure the system in place works. Alarm tests should be documented. The DI should also ensure that temperatures are reviewed for trends which may help in identifying storage conditions which may be deteriorating and will alert staff to developing equipment failure.
13.	PFE3(b)	To ensure staff are aware of where relevant material is stored, freezers and liquid nitrogen tanks containing human tissue should be appropriately labelled, and should contain the contact names and phone numbers of the relevant staff to contact in the event of an emergency.
14.	N/A	As per standard condition 8, Annex B of the Research sector licence, a copy of the licence is displayed in the building's central entrance area. The DI is asked to display a copy of the licence in all areas where relevant material is being stored under the licence.
15.	N/A	The DI may wish to add additional PDs to the licence who may be working with human samples and involved in liaising with establishments providing the samples.

Concluding comments

There are a number of areas of practice that require improvement, including two minor shortfalls.

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: 14 July 2017

Report returned from DI: 01 August 2017

Final report issued: 08 August 2017

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: 12 January 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.