Site visit inspection report on compliance with HTA licensing standards

Robert Jones and Agnes Hunt Orthopaedic Hospital

HTA licensing number 12073

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **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;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

31 October & 01 November 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 Robert Jones and Agnes Hunt Orthopaedic Hospital had met the majority of the HTA's standards, shortfalls were found against the governance and quality standards, particularly in relation to audits and risk assessments not being completed.

Particular examples of strengths 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 Robert Jones and Agnes Hunt Orthopaedic Hospital (the establishment). The Designated Individual (DI) is a Consultant Spinal Surgeon; the Corporate Licence Holder (CLH) is Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust; and the CLH contact is the Director of Operations.

Anatomy department
The Anatomy department is staffed by one full time member of staff who is listed on the licence as a Person Designated (PD). A second PD works under the governance of the licence and teaches professionals. At the time of the inspection, a laboratory assistant was employed to assist the PD with laboratory work.

The facility is used to teach a range of professionals including nurses, radiographers, and physiotherapists. Typically, three bodies are stored and used for teaching at any given time and each body remains at the establishment for a maximum of three years. The establishment has service level agreements (SLAs) with a number of HTA-licensed establishments that provide the bodies, arrange transportation and delivery, and also embalm the bodies. No embalming of the bodies takes place at the establishment. The bodies are received into the anatomy department, at an agreed delivery time, via a side door which is secluded from the hospital and is monitored by CCTV surveillance. Bodies are dissected by the DI and PD in preparation for teaching.

The anatomy laboratory contains four post mortem style dissection tables with a basin connected to each table and an adjacent sluice room. The anatomy laboratory also contains a large number of potted museum specimens that are recorded on a database and pre-date the commencement of the Human Tissue Act 2004 (HT Act). There is an additional storage area for whole bodies and retained parts that consists of four freezer spaces and 12 fridge spaces. The fridge and freezers temperatures are recorded manually on a daily basis and these temperature records are reviewed for trends. The fridge and freezers are not connected to an external monitoring system, however the material currently stored is embalmed and there is minimal risk to the integrity of the tissue if it is stored at room temperature. The anatomy lab does have a contingency agreement with a local mortuary if needed.

All bodies are labelled with a unique identifier which is applied by the sending establishment. The number of tags varies between establishments but, at a minimum, all bodies will have a tag in an ear. The unique identifier is recorded on the associated documentation received with the body, and is used to ensure the body is the correct body (see shortfall against T1(c)).

Occasionally the establishment will host surgical skills training for surgeons. Course participants are usually internal clinical staff; however, there have been no surgical training courses for a number of years. Cadaveric material, usually upper and lower limbs, are acquired or loaned from an HTA-licensed establishment in advance of the course. Once the

course is completed, the body parts are either returned to the establishment they came from or appropriately disposed of. The hospital has a well-documented disposal policy for human tissue given the nature of operations undertaken at the establishment.

Research Tissue Bank

In June 2017, ethical approval was granted for a research tissue bank (RTB) at the establishment. The RTB utilises the anatomy sector storage licence; however, there are also three other RTBs under another HTA licence (see *Advice*, item 17).

The RTB, RJAH Biobank for studying health and disease, stores tissue from patients with osteosarcoma. Samples were originally stored as part of the diagnostic record; however, since setting up the RTB, consent is being retrospectively sought from patients who are still attending the clinic for treatment. These patients, and prospective patients, are identified by the Biobank manager during multidisciplinary team meetings (MDT) and consent is sought by fully trained specialist nurses. Where patients decline donating their tissue, the tissue is not added to the RTB but it is continued to be stored as part of the diagnostic record.

The RTB holds samples with consent from approximately 70 patients. Samples include frozen tissue; formalin-fixed paraffin-embedded tissue; blood; sputum; saliva; faeces and urine. An additional 650 patients have tissue stored as part of their diagnostic records; however, until consent has been sought, this tissue will not be stored in the RTB. Requests for tissue will be made directly to the Biobank manager who will forward them to the Biobank Access Committee. Members of the committee will review the request and determine whether the study is appropriate for tissue to be released.

Samples are stored at room temperature; in one -80°C freezer; one -20°C freezer; and one liquid nitrogen (LN2) dewar. Temperatures are monitored, and the freezers and liquid nitrogen dewar are linked to a remote call out system which alerts staff to temperature deviations (see *Advice*, item 12). The room where the LN2 dewar is stored has a personal oxygen alarm which is being incorrectly used (see *Advice*, item 15).

The RTB is in its infancy and the tissue has not yet been released for use in research. As a result, many documents are incomplete and do not accurately reflect practice (see shortfall against GQ1 (a)).

Description of inspection activities undertaken

The inspection consisted of a visual inspection of the RTB; a visual inspection of the anatomy department; documentation review; interviews with a consultant surgeon; the PD; the Biobank manager; the DI; and the Director of Operations (CLHc).

Traceability audits of all three bodies stored in the anatomy department were carried out. Labels on the bodies were noted and checked against the documentation, including completed consent forms. On one body the label and the reference number recorded on the documentation did not match (see shortfall against T1(c)).

Traceability audits were carried out of eight samples stored in the RTB under different conditions, including at room temperature, -20°C, 80°C and in LN2. Samples were identified from their storage location and traced to the relevant documents, in addition to being selected from the database and traced to their storage locations. No anomalies were found.

Inspection findings

The HTA found the Licence Holder, and the Designated Individual and the premises to be suitable in accordance with the requirements of the legislation. The RTB is currently located in the Department of Pathology which is not covered by the HTA licence. This was discussed with the DI during the inspection and it was agreed that the licence would be extended to the Arthritis Research Centre, where both the Department of Anatomy, and the Department of Pathology are located.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified 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.	**RTB** Although documents have been written for a number of activities under the RTB, they are incomplete, and not fit for purpose. For example: • SOP BB05 'Storage Inventory and Disposal' is not clear and does not provide a step by step process for logging and storing samples. For example, samples are temporarily stored at -80°C until the box is full, and then they are transferred to LN2 storage. This information is not detailed until page 6 of the SOP. The method through which tissue is disposed of and recorded is not detailed in the SOP. In addition, details of how unique identifiers are added to each sample are not adequately described. • SOP BB06 'Request and allocation – process for recording request for samples and monitoring use' does not provide any detail about this process, simply refers to a relevant SOP. In addition, documents reference previous versions of the HTA's Codes of Practice. *See Advice, item 1*	**Major**
d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff.	**Anatomy and RTB** While the DI informally meets with the PD on a regular basis, there are no formalised meetings where matters such as incidents or audit findings can be discussed. Since the scope of the licence has increased to include the RTB the importance of having formalised meetings to discuss HTA-related matters has increased.	**Minor**
GQ2 There is a documented system of audit.		

a) There is a documented schedule of audits covering licensable activities.	**RTB** Staff working under the governance of the RTB have written an SOP detailing how an audit should be conducted, however no audits have been conducted, and there is no schedule of audit in place. Audits of sample traceability; consent; and documentation for content and accuracy are not currently undertaken. *See Advice, item 3*	**Minor**
GQ5 There are systems to ensure that all adverse events are investigated promptly.		
a) Staff are instructed in how to use incident reporting systems.	**RTB** There is no formalised, documented system for staff report to report incidents relating to relevant material. *See Advice, item 5*	**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.	**RTB** Documented risk assessments were not provided during the inspection and it is not evident that the risks to the tissue have been appropriately considered. *See Advice, item 6*	**Major**

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, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.	**Anatomy** During the audit of stored bodies it was noted that the unique number on the ear tag of one body did not match the associated consent documentation. This had not been previously noted by establishment staff. *See Advice, item 9*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	**Anatomy** A number of the documents have not been updated to reflect current practices. For example, SOP/ANAT/06 'Receipt of cadavers' refers to receiving bodies from Keele Medical School only; however, bodies are routinely received from a number of other establishments. The DI should ensure that all documents related to licensed activities are reviewed to ensure they are adequately detailed, and provide up to date information. **RTB** Where documents refer to another SOP for further information, these documents should be cross referenced to ensure the process that should be described is included. For example SOP BB03 'Sample Preparation and Quality Manual' references SOP BB05 'Storage Inventory and Disposal' for further information on labelling procedures and not using samples for diagnosis once a cryovial has been opened; however, this process is not detailed in SOP BB05. The Biobank manager should ensure that all references to previous versions of the HTA's Codes of Practice are removed and replaced with updated ones. Where appropriate, SOPs should be merged and unnecessary SOPs archived.
2.	GQ1(b)	**Anatomy** Documents which have been reviewed or written in 2017 do not have a 'review by' date. The DI is advised to ensure that all documents in use include a date by which they must be reviewed. This will ensure that documents are reviewed at appropriate time points, and that they are kept up to date as procedures evolve. **RTB** Documents pertaining to the RTB have been authored and approved by the Biobank manager, which is suboptimal practice. Documents should be written and approved by different people.
3.	GQ2(a)	**Anatomy**

		The PD carries out quarterly audits on stored specimens and records. Currently, the audit form is ticked to indicate compliance, however the DI is advised to consider documenting the samples audited, including any findings or non-conformances and how these were addressed. During the traceability audit conducted by the HTA a discrepancy, as described under the Shortfall T1(c), was noted. Documenting the specimens, including the cadavers examined as part of the regular audits may have led to earlier detection of this discrepancy. **RTB** Minor discrepancies noted during the audits performed during the inspection, for example, incomplete entries on the database would have been picked up if effective, regular audits were being conducted.
4.	GQ2(b)	**Anatomy and RTB** The DI is advised that audit findings and corrective and preventative actions should be recorded, and should include timeframes for completion. Audit findings should be shared across all groups working under the licence.
5.	GQ5(a)	**RTB** The DI should create and implement a system where adverse events related to relevant material are reported to him. While there is currently no requirement to report adverse events in the research and anatomy sectors to the HTA, the DI should be made aware of all adverse events and we encourage contacting us if there are particular concerns. Relevant examples of adverse events include: • specimen loss; • missing or incorrect documentation; • security breach; • abnormalities in storage temperature readings; • inappropriate disposal. All incidents should be appropriately investigated, which includes a root cause analysis and follow-up actions.
6.	GQ6(a)	**Anatomy** Currently the suite of risk assessments relating to the anatomy licence are held on the Trust Datix system. The DI should consider creating a risk matrix which captures all risk assessments in one document. **RTB** While risk assessments are in place, the Biobank manager is advised to ensure that the risks relating to the premises, practices and procedures connected with licensed activities have been considered. These should include: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • storage failure or other damage affecting human tissue quality for useful research;

		• loss of human tissue; • sample mix-up or loss of traceability; • transport of specimens to and from the establishment; • security arrangements; • incorrect disposal.
7.	GQ6(b)	**Anatomy and RTB** 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.
8.	T1(a)	**RTB** The database used to record samples held in the RTB had not been updated for a number of weeks. This represents a risk to sample traceability, with new samples not being recorded. The DI should ensure that all samples are immediately added to the database, and regular audits should be performed to confirm currency.
9.	T1(c)	**Anatomy** Even though the discrepancy between the number on the body and the number on the consent paperwork was quickly rectified during the inspection, this had not previously been noted. The DI should ensure that a robust system is in place which details the steps taken when an anomaly arises.
10.	T1(c)	**RTB** The DI is advised to ensure that all storage units indicate that human tissue samples stored under the HTA licence are contained within. The units should be numbered with an identification number. This will help to ensure sample traceability records accurately reflect the storage location.
11.	T2(a)	**RTB** While the method and reason for disposal are recorded, the date is not. To date no material has been disposed of, however, the DI is advised to ensure that the database used to record sample traceability updated to include the date, method and reason for disposal. All associated SOPs should be updated to reflect this change too.
12.	PFE2(c)	**RTB** While freezers and the LN2 tanks are linked to remote call out systems which alert staff to temperature deviations, records are not reviewed for trends. The DI is advised to ensure a regular review for trends is undertaken. This will allow staff to identify when storage conditions may be deteriorating and might alert staff to impending equipment failure.
13.	PFE2(d)	**RTB** During the inspection the HTA were informed of informal contingency arrangements in place with other researchers at the establishment. The DI is advised to formalise these arrangements to ensure alternative storage arrangements are identified in the event of a failure.
14.	PFE3(c)	**RTB**

		All staff responsible for adding or removing samples from storage areas must ensure personal protective equipment is used at all times. During the inspection several practices which may cause significant harm to individuals were observed, including wearing insufficient personal protective equipment when accessing samples stored in LN2.
15.	PFE3	**RTB** LN2 dewars are stored in an external store and one personal oxygen depletion monitor is used to monitor the oxygen levels of the entire store. The personal monitor is not worn by staff, instead it is mounted on the wall. This is an inappropriate use of the oxygen depletion monitor. Due to the manner in which LN2 leakages deplete oxygen following a spillage, the DI is advised to assess the risk of the oxygen monitors failing to detect oxygen depletion, as a result of LN2 spillage, due to their design, location and intended use
16.	N/A	**RTB** The DI is advised to add a PD to the licence who is responsible for the RTB. The name of this person should be notified to the HTA.
17.	N/A	**RTB** Three additional RTBs are stored at the establishment under a separate licence. The DI may wish to consider transferring the governance of RJAH Biobank for studying Health and Disease to the separate licence as this may provide consistency in the management and governance of the RTBs at the site.

Concluding comments

A number of areas of strengths were noted during the inspection, including:

- Large range of documented SOPs for the anatomy laboratory
- The premises and facilities within the anatomy department provided by the establishment are secure and well maintained

There are a number of areas of practice that require improvement, including two major shortfalls and four 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: 22 November 2017

Report returned from DI: 07 December 2017

Final report issued: 08 December 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: 11 May 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. 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 supported by ratified 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-licensable 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, the consent obtained, 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) 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.