Site visit inspection report on compliance with HTA minimum standards

Newcastle upon Tyne Hospitals NHS Foundation Trust

HTA licensing number 12193

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**

6 November 2014

Summary of inspection findings

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

Although the HTA found that Newcastle upon Tyne Hospitals NHS Foundation Trust ("the establishment") had met the majority of the HTA standards, three minor shortfalls were found in relation to governance and quality systems. The HTA has given advice to the Designated Individual with respect to the standards relating to consent and governance arrangements.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Newcastle upon Tyne Hospitals NHS Foundation Trust ("the establishment") is licensed by the HTA under the Human Tissue Act 2004 for the storage of relevant material for use for scheduled purposes. This licence applies to premises at the Royal Victoria Infirmary.

The establishment stores relevant material for use in research as part of two diagnostic archives for: Neuromuscular Disease, and Cellular Pathology. The diagnostic archives also function as research tissue banks (RTBs) since samples may be released for use in research. The two diagnostic archives are stored separately at the establishment and are subject to distinct operating procedures, under the overall governance of this licence.

The establishment uses electronic databases and paper-based records to provide traceability of samples. All samples are assigned a unique identification number which is used to track sample receipt, storage, release for use in research and disposal. Samples are stored in dedicated storage facilities in secure locations. Freezer temperatures and liquid nitrogen levels are continually monitored and there is an alarm with a robust call-out notification procedure in the event of a deviation from the set acceptable ranges. Freezers and temperature monitoring probes are regularly maintained and calibrated and the establishment has contingency arrangements for storage in the event of equipment failure. The specific arrangements and operation of each RTB stored under this HTA licence are described below.

The Neuromuscular Disease diagnostic archive receives tissue samples from a number of organisations, as part of the establishment's role as a national diagnostic referral centre. The archive consists of fresh tissue samples obtained from living and deceased people. Samples are stored in -80°C freezers and in vapour phase liquid nitrogen. Samples obtained post-mortem are stored in cryoboxes separately from tissues obtained from living people. All samples in this archive are tracked using paper-based records and an electronic database.

The Neuromuscular Disease diagnostic archive has received RTB research ethics committee (REC) approval (REC 08/H0906/143); including generic ethical approval for projects receiving material from the tissue bank for research use. Samples obtained from living people are de-identified and released for use in research. Post-mortem samples are released for use in research where valid consent has been given. Consent for the removal and use of post-mortem tissues in research is sought at the organisation from which the samples originate. The establishment performs checks on consent forms and maintains a record of post-mortem samples for which consent has been given for use in research. Sample release is managed by a small group of staff at the establishment who update the traceability records, including recording the details of research groups receiving samples. Distribution of these samples is undertaken by another HTA-licensed establishment under a Service Level Agreement with this establishment.

The Cellular Pathology diagnostic archive consists of paraffin-embedded and fresh tissue samples obtained from living and deceased people. Paraffin-embedded tissue blocks and slides are stored at room temperature in a dedicated storage room. Frozen samples are stored in -80°C freezers and in vapour phase liquid nitrogen. All paraffin-embedded tissue blocks and slides and the majority of frozen tissue samples are tracked using an electronic database for each collection of tissues. Frozen tissues obtained prior to 2010 are tracked using a paper-based record only.

Samples in this Cellular Pathology archive are stored primarily for diagnostic purposes. Tissue samples from living people may be anonymised and released for use in research which has received approval from a recognised REC. Traceability records are updated to include the details of samples released from the archive. There is a robust procedure for release of samples from this archive and the HTA has provided advice to further improve documented procedure for this process (see Advice item 5).

Following completion of initial diagnosis, some samples in the Cellular Pathology archive may be identified to be of interest to the Children's Cancer and Leukaemia Group (CCLG). The national CCLG RTB (REC 08/H0405/22) is stored at another HTA-licensed establishment. Suitable samples in the Cellular Pathology archive may be transferred to the CCLG RTB with approval from the treating clinician and valid consent. Consent may also be sought for blood samples to be collected and stored for use in research, including for DNA analysis. Blood samples are obtained by clinical staff during the course of planned clinical procedures. Consent is sought in accordance with the CCLG RTB standard operating procedure (SOP). Participant information sheets and consent forms are provided by the CCLG RTB and have been ethically approved by the REC. Clinical staff seeking consent receive training in Good Clinical Practice. Separate participant information sheets and consent forms are used for participants of different age ranges or, in cases where the child is deemed to lack capacity to give consent, their parent or guardian. The establishment currently only transfers samples from living persons for storage in the CCLG RTB. Consent forms are stored at the establishment and written confirmation of consent is provided to the CCLG RTB.

The subsequent storage of samples in the CCLG RTB and release of these samples for use in research is undertaken at another establishment and under the authority of a different HTA licence. These activities were therefore not included in this site visit inspection.

The establishment has been licensed by the HTA since February 2008. This report describes the first, routine, site visit inspection of the establishment in November 2014. The timetable for the site visit inspection was developed in consideration of the establishment's licence application, compliance update information and discussions with the Designated Individual (DI). The site visit inspection included a visual inspection of the areas where relevant material is stored under this licence, a review of documentation and meetings with establishment staff.

An audit of traceability records and consent forms was conducted for: frozen tissues from living and deceased persons in the Neuromuscular Disease diagnostic archive; paraffin-embedded tissue blocks and slides in the Cellular Pathology archive, and; frozen tissue in the Cellular Pathology archive. These audits revealed no anomalies in the storage locations or number of samples. An audit of legibility and completeness of consent forms was conducted. One consent form for post-mortem samples in the Neuromuscular Disease RTB and three consent forms for samples transferred to the CCLG RTB were reviewed. Examples of minor inconsistencies were identified in the dates recorded on two of the three CCLG RTB consent forms examined and the HTA provided advice regarding on-going audit of such documents.

The establishment informed the inspection team that two other departments at this site also store relevant material intended for use in research at another HTA-licensed establishment. However, since these samples are stored pending transport and for less than seven days, storage of these samples is exempt from the licensing requirements of the Human Tissue Act 2004. These samples were not included in the visual inspection or audit trail.

The establishment stores paraffin-embedded tissue blocks and slides from the Cellular Pathology diagnostic archive, which are over three years old, in a separate archive at a different site. The inspection team was informed that these archived diagnostic samples are not released for use in research. Since this archived Cellular Pathology collection is not functioning as a RTB, this off-site storage location is not included in this HTA licence and was not inspected as part of this site visit. The DI was advised to contact the HTA should this archived Cellular Pathology tissue collection be intended to be used as a RTB in the future.

Inspection findings

The HTA found the Designated Individual and the Licence Holder 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 establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The over-arching governance framework for the storage of samples under the authority of this HTA licence should be developed further. There are currently no formal governance meetings. *(See Advice item 4)*	**Minor**
GQ2 There is a documented system of quality management and audit.	The establishment has not undertaken audits of stored human tissues or records of traceability and consent. There is no documented schedule of audits. *(See Advice item 6)*	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has a limited scope of documented risk assessments, all of which relate only to health and safety risks. There are no documented risks assessments of the regulatory risks associated with the storage of human tissues for use in research. *(See Advice item 7)*	**Minor**

Advice

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

No.	Standard	Advice
1.	C2	The DI is advised to consider seeking review of the consent documentation for the CCLG RTB to ensure that the printed documents have unique document titles. This may help to differentiate between the documentation used to seek consent for use of tissues from living and deceased, in order to ensure that information about the consent process is provided appropriate to the situation.
2.	C2	The establishment uses a "DNA Registration Form" as part of the consent process for samples in the CCLG RTB. This ensures that consent for the use of these samples for research, including DNA analysis, is fully informed. The DI may wish to seek review of the CCLG participant information sheets to also provide information that samples may be used for DNA analysis.

3.	C3	Staff seeking consent have received training in Good Clinical Practice. The DI is advised to ensure that that all staff seeking consent receive periodic refresher training and that records of staff completion of refresher training are maintained.
4.	GQ1	To support the implementation of regular governance meetings, the DI should introduce formal agendas for meetings to discuss licensable activities. These meetings may cover items including: changes to SOPs, adverse incidents, audits and their findings, risk assessments and HTA training. Minutes of these meetings should be documented, including the timelines for identified actions, and circulated to all relevant staff. Regular governance meetings will help the DI to maintain oversight of licensable activities undertaken under the authority of this HTA licence.
5.	GQ1	The DI is advised to update the SOP for release of samples for research from the Cellular Pathology archive (SOP HIML138) to document the checks that staff currently perform to ensure that samples are not labelled with patient identifying information. This will provide further assurance that all samples released for use in research are pseudo-anonymised.
6.	GQ2	To support the introduction of regular audits, the DI is advised to develop a documented audit schedule to include audits of each diagnostic archive. These audits could include vertical audits of the traceability of human tissue, from records of receipt to storage, use or disposal, and horizontal audits. Records of traceability and consent should be audited to check for completeness, legibility and accuracy. The results of audit findings and actions taken should be formally recorded. This will help the DI to further assure himself of the robustness of tissue traceability systems and consent processes for each of the RTBs.
7.	GQ4	The establishment uses a paper-based record to provide traceability of an older collection of frozen samples in the Cellular Pathology archive. The DI is advised to risk assess the use of this paper record and consider creating an electronic back up to ensure that traceability of these samples is maintained.
8.	GQ8	The DI should document risk assessments for the risks associated with the storage of human tissues and non-compliance with the Human Tissue Act 2004. These risks may include, for example: • storage of relevant material without consent; • failure of storage facilities, and; • loss of traceability of relevant material. The DI is advised to ensure that these risk assessments are reviewed regularly and that all staff undertaking licensable activities are aware of these risk assessments.

Concluding comments

This report outlines the first HTA site visit inspection of Newcastle upon Tyne Hospitals NHS Foundation Trust. There were a number of areas of good practice observed during the inspection. The premises and storage facilities are well-maintained and there are comprehensive temperature monitoring and alarm call-out procedures. The consent process for samples being transferred to the CCLG RTB is robust and well-considered. The establishment uses participant information sheets and consent forms tailored to different participant ages and for parents and guardians. The HTA has given advice to further improve documentation of the CCLG consent process, including audits of completed consent forms.

There are some areas of practice that require improvement, as indicated by the three minor shortfalls in relation to the governance and quality standards. The HTA has given advice to the Designated Individual with respect to consent and governance and quality arrangements.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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: 28 November 2014

Report returned from DI: 2 December 2014

Final report issued: 2 December 2014

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: 1 April 2015

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • 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
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

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.