Site visit inspection report on compliance with HTA minimum standards

Anglia Ruskin University (Cambridge East Road Campus)

HTA licensing number 12515

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**

15 March 2017

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 Anglia Ruskin University (Cambridge East Road Campus) (the establishment) had met the majority of the HTA standards, six shortfalls were found, relating to consent documentation, audits, governance meetings, adverse event management and records of disposal.

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 licenses 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

This report refers to activities carried out at Anglia Ruskin University (Cambridge East Road Campus) (the establishment). The establishment is licensed for the storage of relevant material for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The establishment has been licensed since 2008 and was last inspected in 2011. This inspection was the second routine site visit inspection.

The Designated Individual (DI) is a Senior Lecturer in Biological Psychology at the establishment. The Corporate Licence Holder is Anglia Ruskin University, and the Corporate Licence Holder contact (CLHc) is the University's Secretary and Clerk. There is one Person Designated (PD) under the licence.

All research studies undertaken at the establishment are subject to a review by the University's local ethics committee. Researchers must complete an application form for each study they plan to undertake, which highlights if human tissue will be stored and used. There are different levels of approval required from the University, depending on the nature of the study. Researchers using human tissue must seek approval from the Faculty Research Ethics Panel (FREP). At the time of inspection, the DI was temporarily chairing this committee, however, he is usually a member of the panel.

Blood and saliva samples are stored at the establishment for use in research. The Saliva Analysis Laboratory provides an analysis service for organisations in the UK and Europe. Saliva samples are received from healthy volunteers and are analysed and disposed of at the establishment. These samples are stored and used for the scheduled purposes of: 'Research in connection with disorders, or the functioning, of the human body'; and, 'Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)'. Staff and students recruit and seek consent from healthy volunteers for research projects relating to stress. Staff and students at the establishment are provided with training on seeking consent and appropriate ethical approval. Students working directly with the DI are also provided with additional training related to the HTA (see Advice, item 2).

Hair is also stored and used for research projects at the establishment; however, this is not subject to the licensing requirements under the HT Act since the hair is from living donors.

The establishment's human tissue collections, stored under the HTA licence, are held in the Faculty of Science and Technology, in a secure laboratory. Samples are stored in three -80°C freezers and one -20°C freezer. The freezer alarms are linked to a remote call-out system which alerts staff to temperature deviations. Temperature trends are reviewed on an ad hoc basis. At the time of inspection, the battery life of the temperature sensor was diminishing, and as such the alarms were triggering more frequently (see Advice, item 10).

External organisations wishing to have saliva samples analysed at the establishment must first contact the PD. The PD reviews the application information, including information on the consent process, and approves the applications, where appropriate. The PD creates and sends barcode labels to the organisation; these labels are affixed to the sample tubes prior to shipment to the establishment. When the samples are received in the laboratory, they are entered into the Laboratory Information Management System (LIMS). The establishment uses the LIMS database to record sample information, including: which freezer the samples are stored in; details of the types of samples; when they were taken; and, date of disposal. However, the LIMS is not used to record the reasons for disposal of samples (see shortfall against D2). Blood samples entering the laboratory also use the same system. Undergraduate students collecting samples do not have access to the -80°C freezers. Instead, they place samples in the -20°C freezer and consent forms in a tray in the laboratory; the PD logs the samples into LIMS and files the consent forms (see Advice, item 9).

One PD has oversight of these collections and is responsible for maintaining and updating the LIMS. Currently, there are two collections stored under the licence; however, the establishment is planning on increasing the number of samples held on site in the coming months (see Advice, item 15).

The inspection comprised of a roundtable discussion with members of staff working under the licence, a visual inspection of the laboratory where human tissue is stored under the licence, interviews with the Laboratory Manager (PD), a Senior Lecturer in Sport and Exercise Sciences, a PhD student, the CLHc and the DI, and a review of governance documentation.

In addition, traceability audits were carried out for four samples stored at -80°C and one sample stored at -20°C. Samples were identified from their storage locations and traced to relevant documents. One anomaly in sample traceability was identified, where a sample had been recorded as disposed of, on the researcher's local sample database. This sample was, however, correctly recorded on LIMS, meaning that sample traceability could be maintained (see Advice, item 5).

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 DI meets with the PD on a regular basis. However, there are no formal meetings where issues related to the licence, including audits, incidents and corrective and preventative actions, can be discussed. Given the number of shortfalls to be resolved and, in light of more groups expected to be working under the licence, formal governance meetings will become increasingly important. *See Advice, item 3.*	**Minor**
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment's documented policies and procedures need reviewing to ensure that they are accurate and reflect current practices. Examples of the policies and procedures that need review include, but are not limited to: • The standard operating procedure (SOP) for transport of samples. This document does not detail the use of the sample manifest and checks that are performed of this upon receipt of samples to the establishment; • 'Faculty of Science and Technology Standard Operating Procedure: Human Tissue'. This document refers to the National Research Ethics Service, which is now part of the Health Research Authority, and the HTA "Codes of Conduct", which are actually the Codes of Practice; • Documents often refer only to saliva samples, and have not been updated to include other relevant material stored under the licence; for example, blood.	**Minor**

GQ2 There is a documented system of quality management and audit.	The establishment is not currently undertaking traceability audits of samples stored under the licence, or audits of records for content and accuracy. There is no schedule of audits in place. *See Advice, item 5.*	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.	Incidents related to human tissue are not logged and recorded, and there is no system in place for investigation and follow-up actions. There is no written evidence to demonstrate clear lines of accountability for reporting adverse events.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	While there are risk assessments relating to human tissue, the risks related to storing samples without appropriate consent have not been assessed formally. *See Advice, item 7.*	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The LIMS is not used to record the reason for disposal of samples. The establishment's SOPs for sample traceability and disposal do not provide details of what records of disposal must be made. Although most samples are disposed of due to study completion, the establishment has disposed of samples for other reasons, and these reasons have not been recorded.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	Under the HT Act consent is required for the storage and use of relevant material for a scheduled purpose. The DI is advised to review the consent forms used to ensure storage of relevant material is captured. The consent forms and patient information sheets do not provide sufficient information about how a participant may withdraw from a study, or the contact details of who to contact if they wish to withdraw. Although the template

		consent form has been modified for use in studies, the consent form seen on inspection has not been reviewed since 2004. In addition, the individual seeking consent does not sign or date the consent form.
2.	C3	Researchers working with relevant material, under the direct supervision of the DI, are provided with a 'HTA Briefing' training session before beginning their research. This is a valuable learning tool for training in the requirements of seeking appropriate consent and the HT Act, and the DI is advised to extend this training package to all researchers working with relevant material under the licence.
3.	GQ1	All staff working under the licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment.
4.	GQ2	The DI is advised to ensure that all standard operating procedures (SOPs) and forms are version-controlled, and that staff are using the most up-to-date versions. Forms that have been created from a template should contain their own document control information and not that of the template. If a written amendment is added to a document (for example, to a consent form), the DI should ensure that these amendments are signed and dated so that the most up to date form is used.
5.	GQ2	The DI is advised to ensure that the audit schedule includes vertical audits of records and samples, from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Audits should also ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded, including timeframes for completion of actions and confirmation that all required actions have been completed. Audits should be undertaken on a periodic basis and following changes to processes; for example, when additional groups begin storing samples under the licence.
6.	GQ6	The DI is advised to ensure that all sample traceability records, including local records maintained by each researcher, are kept up-to-date. When an audit schedule has been created, the DI should ensure that the audits extend to include all sample traceability records, including local of sample traceability databases. This will help to highlight any anomalies in these records and will provide assurance to the DI that documentation accurately reflects the status of a sample.
7.	GQ8	While risk assessments are in place, the DI should expand the risks assessed to include the following: • storing or using human tissue after consent withdrawal; • storage failure or other damage affecting human tissue quality for useful research; and

		• incorrect disposal The establishment's risk assessments should be reviewed to ensure that they contain sufficient details of the risks and mitigating actions. 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.	PFE1	The laboratory where relevant material is stored is in a remote area of the establishment and staff often work alone. The lone working alarm is currently tested on an ad hoc basis. The DI is advised to formalise this testing to help to mitigate the risk of this alarm failing and its failure going undetected.
9.	PFE3	The DI is advised to review the arrangement for intermediate storage of completed consent forms in the laboratory. These forms are currently placed in a filing tray on the laboratory workbench, until a member of the laboratory staff processes the samples (in the -20°C freezer) for storage in the main (-80°C) freezers. The DI is advised to consider whether there is a more suitable arrangement for storage of these forms to ensure that they are secure and protected from potential damage; for example, from a spillage.
10.	PFE3	While freezer temperatures are reviewed for trends, this is done on an ad hoc basis. The DI should formalise this procedure to ensure any deviations in freezer temperature are noted and acted upon promptly. This will also allow staff to identify when storage conditions may be deteriorating and might alert staff to impending equipment failure. This will also provide assurance to the DI that the alarms are working even as the battery life of the temperature sensors decreases.
11.	PFE3	The exact locations of the samples within the freezer are not recorded on the LIMS database, or on the freezer. The DI is advised to create a map of the contents of the freezer, which is regularly updated, to allow for quick location of the samples. This document should be included in the establishment's document control system, and if printed should include the date of printing, to ensure that it is up-to-date.
12.	PFE3	The establishment also stores non-human 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.
13.	PFE4	The DI is advised to review the procedure for transfer of samples to include details of: • Receipt of samples, including information on expected sample numbers, and what checks should be performed to ensure this is correct; • out of hours deliveries; and • the procedure for samples arriving without staff being notified. The SOP relating to transport of samples should be reviewed and a risk assessment of transport and traceability records should be included. Where a sample manifest is used, details of this should be included in the SOP. The saliva and project overview documentation should be reviewed to clarify the length of time for which samples will be stored.

14.	N/A	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 the laboratory where samples are stored.
15.	N/A	As the number of groups working under the licence expands, the DI is advised to appoint more PDs in these areas to assure himself that appropriate practices are being followed.

Concluding comments

During the inspection, areas of good practice were noted, including a good working relationship between the DI and PD, and other staff working under the licence. The DI and PD demonstrated good understanding of the requirements of the HT Act and the HTA's Codes of Practice. The establishment has a robust tracking system, which ensures all samples received to the laboratory are labelled using the same barcoding system, and allows for the easy location of samples and associated documentation.

There are a number of areas of practice that require improvement, including six minor shortfalls. The HTA has also given advice to the Designated Individual on a wide range of matters.

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: 07 April 2017

Report returned from DI: 26 April 2017

Final report issued: 05 May 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: 04 May 2017

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.