Site visit inspection report on compliance with HTA minimum standards

St Mary's University

HTA licensing number 12615

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**

11 March 2015

Summary of inspection findings

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

Although the HTA found that St Mary's University (the establishment) had met the majority of the HTA standards, some minor shortfalls were found against the Consent (C) and Governance and Quality Systems (GQS) standards. These were in relation to consent for storage, the carrying out of audits and the lack of risk assessments in relation to human tissue stored by the establishment.

Advice has been given relating to C, GQS and Premises, Facilities and Equipment (PFE) standards. It is recognised that the establishment has been licensed for only ten months and is in the process of developing its systems.

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

This report refers to the activities carried out at St Mary's University (the establishment), specifically within The School of Sports, Health and Applied Science (SHAS).

The establishment has been licensed since May 2014 for the storage of relevant material for use for a scheduled purpose. The scheduled purpose applicable to this licence is research in connection with disorders, or the functioning, of the human body.

Research plays a prominent role at SHAS, with studies relating to a range of sport topics including performance, nutrition, health and exercise. Some of this research involves the storage and use of relevant material, currently whole blood and plasma from the living. Donors for current studies are mainly healthy volunteers who are students. The establishment considers the plasma it stores and uses to be relevant material under the Human Tissue Act 2004.

The laboratories have been part of the British Association of Sport and Exercise Sciences (BASES) accreditation scheme since 2007. 'BASES laboratory accreditation' is a voluntary scheme, subject to a fee, which aims to provide assurances regarding the appropriateness of a laboratory to conduct physiological testing.

This was the establishment's first routine inspection since being licensed last year. It consisted of a visual tour of the facilities where licensable activity takes place, a traceability

audit, document review and interviews with the DI, the Technical Services Manager who is a person designated under the HT Act (PD) and the Academic Director (PD).

Governance

There are good channels of communication between the DI, the PDs and the CLH contact. There is a Human Tissue Group where any issues that may arise in relation to storage and use of human tissue may be discussed. Issues that require escalation for further action can easily be communicated to the overall University Management. Students and staff use the *Use of Human Tissue guidance document* (HSGN19b), which is an overarching manual of the SHAS policies and procedures for people working with human tissue. The manual describes a range of processes from ethics approval, procurement and storage right through to disposal. However, there were some gaps identified in HSGN19b because at the time of the inspection the establishment was optimising its systems and procedures.

Consent and ethical approval

All research studies go to the University Ethics Committee for approval. As part of the application process, the consent information sheet and a copy of the consent form study participants will be asked to sign are provided. Consent from participants for individual studies is sought in the laboratory and there is a consultation room available for privacy if the laboratory is busy. The consent forms also include a health screening questionnaire.

A horizontal consent audit was performed during the visual inspection, where samples in the freezer were used to confirm that relevant consent was in place. It was found that the current system, where consent forms are kept by each researcher, made it difficult to demonstrate that consent is in place for each sample.

Storage

Samples are stored in -80°C freezers in two different buildings: the Centre for Health, Applied Sport and Exercise Science (CHASES) building and the Human Performance Laboratory 1 (HPL1). Both buildings were visited as part of the inspection process. There is also a -20°C freezer in HPL1, for overnight sample storage only, if the other freezers are not accessible out of hours. Samples from this freezer are then transferred to the -80°C for long term storage. Samples are stored in bags or boxes clearly labelled with their unique identification number.

The -80°C freezers are monitored externally and an SMS callout system is initiated if the freezer temperatures fall outside a pre-defined range. The callout system sends text messages to an identified group of people, who are all aware of the process to follow. Temperature excursions outside the set ranges also trigger an audible alarm.

The -80°C freezers are also manually monitored twice-daily to ensure they are within the correct temperature range. The establishment records the temperatures on a log sheet which is kept in the laboratory.

Traceability audit

As part of the inspection, a traceability audit of four samples was conducted; one from the freezer in the CHASES lab and three from the HPL1 freezer. Their details were compared with those in the tissue logs and no anomalies were found.

Inspection findings

The HTA found the Designated Individual to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
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.	There are two template forms referenced in HSGN19b in relation to obtaining consent: the information sheet and the informed written consent form. The information sheet is very comprehensive and provides information relevant to human tissue storage and use for research purposes. However, the consent form template, in its current format, does not offer provision for the participant to record their consent for their tissue to be stored for research.	Minor
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Consent seeking is part of the syllabus for undergraduate students. However, there is no specific training for staff or post graduate students. *See advice items 1&2*	Minor

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit and partially.	Although the establishment plans to conduct an audit within two months of this inspection, there is no clearly defined schedule of when audits will take place and what they will cover. In addition, there is no SOP in place to clarify how issues identified during audits would be addressed or how corrective actions would be dealt with. This makes it difficult for the establishment to demonstrate that issues identified on audit would be resolved in an appropriate manner and timeframe. *See advice item 3*	Minor

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although the establishment has risk assessments in place for many of its processes, these focus primarily on health and safety and do not currently address the risks associated with the storage, use and disposal of human tissue. *See advice item 7*	Minor

Advice

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

No.	Standard	Advice
1.	C3	In addressing the identified shortfall, the DI could consider enhancing the consent section of the guidance document HSGN19b to include a step-by-step guide on what to do when seeking consent. Consent could also be included in the basic skills sign-off session, which assesses the ability of those new to the department to perform many of the processes required in their research.
2.	C3	The DI should consider putting process audits in place to observe consent being sought from study participants. This could identify any potential additional training requirements or to assess if there is sufficient awareness of the Human Tissue Act by those seeking consent.
3.	GQ2	The DI may wish to consider scheduling regular audits, which could cover consent, compliance with HTA standards, process audits to ensure that SOPs accurately reflect current practices and human tissue traceability. The HTA endorses the current plans for the Research Office to undertake these audits, which could be scheduled throughout the year. Audit findings could be discussed at the quarterly Human Tissue Group meetings. If any issues arise, actions to be taken could be formally recorded and followed up on a regular basis to ensure continuing improvement of processes and practices.
4.	GQ3	The DI may wish to consider including the MRC's 'Research and Human Tissue Legislation e-learning Module', part of the MRC Data and Tissues Toolkit (both of which were developed with input from the HTA), as part of the staff training programme: http://www.rsclearn.mrc.ac.uk/
5.	GQ4	Records are kept in several places; samples and sample logs are in the laboratory but consent forms are normally stored in individual researchers' offices. This makes it difficult for the DI to assure himself that records are complete, legible and accurate. The inclusion of records in the audit schedule will also help to improve the on-going management of records.
6.	GQ6	The current unique coding system, which includes the initials of the researcher as the main differentiation between numbers, works well with a small number of studies. However, the DI is advised to consider how the system will work as the number of people storing tissue increases. This may be particularly relevant where researchers share the same initials and therefore this may increase the risk of duplicating unique identifiers.

7.	GQ8	Although not exhaustive, the DI should consider the broad risks to relevant material, such as: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • inappropriate disposal These risks should be evaluated for each of the collections. Risk assessments should be reviewed regularly and also after changes to key procedures. The DI is advised to ensure that staff have access to such risk assessments and that familiarity with them is incorporated into the staff training programme.
8.	PFE3	Signage on the -80°C freezer in HPL1 is comprehensive and includes reference to the alarm set points. Similar signage should be placed on the freezer in the CHASES laboratory as good practice.
9.	PFE3	Prior to the inspection, the establishment was recording that the temperature of the freezer in the CHASES laboratory was within a specified range by placing a tick on the record sheet. The establishment subsequently amended its approach and began recording the actual temperature instead. As this is good practice, the DI should consider adopting this approach in the HPL1 laboratory. Recording the actual temperatures is useful for trend analysis, which may indicate a problem with the freezer which may adversely affect the quality of the stored samples. The Di is also advised to consider additional partitioning or storage shelves in the freezers, and the use of a location map on the outside of the freezers. These measures may help to reduce the amount of time taken to locate specific samples in the freezer and avoid temperature variations that may occur if the freezer door remains open for too long.

Concluding comments

During the site visit inspection of the establishment, several areas of good practice were noted:

The unique sample coding system used by staff and students not only applies to samples taken, but also to individual aliquots made from primary fluid samples, which aids traceability.

The management team work well together and effective systems are in place to respond quickly to requests for change. The SHAS team takes a conscientious approach to their work and is committed to ensure best practice is applied in all their work.

The basic skills sign-off session, which new researchers must complete, is a good way to identify areas of additional training needed in respect of for research involving human subjects.

The HTA has given advice to the DI with respect to the Consent, Governance and Quality Systems and Premises, Facilities and Equipment standards.

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.

Report sent to DI for factual accuracy: 27 March 2015

Report returned from DI: 13 April 2015

Final report issued: 15 April 2015

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: 30 June 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.