Site visit inspection report on compliance with HTA minimum standards

School of Pharmacy and Biomolecular Sciences, University of Brighton

HTA licensing number 12583

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**

26 March 2013

Summary of inspection findings

The School of Pharmacy and Biomolecular Sciences at the University of Brighton (the establishment) was found to have met the majority of HTA standards. However, two minor shortfalls were identified, relating to traceability and alarm monitoring.

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

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 Paragraph 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

The School of Pharmacy and Biomolecular Sciences (PABS) at the University of Brighton currently stores over 100 samples of relevant material including gastro-intestinal and ocular tissue, faeces, sputum and blood samples. These samples have been obtained from living patients seen either during clinical consultation at another licensed establishment or health volunteers recruited for research studies through the university. Consent for use of relevant material for research purposes is usually obtained by the referring clinician or principal investigator for the research projects in question. There is also a small amount of post mortem material stored within the School for teaching purposes. This includes histology slides and some tissue blocks.

The DI is a Principal Lecturer at the University. The CLHC is the Head of School. There are three Persons Designated (PDs), one of whom is a Senior Research Fellow and has delegated responsibility for activities relating to tissues, blocks and slides.

The establishment has been licensed by the HTA since June 2011. This site visit, undertaken on 26 March 2013, was a routine first inspection, which also provided an opportunity for the HTA to review governance arrangements. The visit included a visual inspection of the premises (sample receipt areas, processing laboratories and storage facilities – freezers and an ambient storage for blocks and slides) and formal interviews with the Designated Individual, the Corporate Licence Holder Contact, the Person Designated and other staff working under the licence.

A traceability audit was carried out on seven samples, including five examples of frozen tissue and two sets of histology slides. Each audit trail included: review of evidence of receipt, consent documentation, storage and data entry onto the establishment's management information system. All tissue samples were labelled and coded. The establishment maintains a bespoke computerised information system to track and trace samples. No anomalies or discrepancies were found on the majority of selected examples during the traceability audits, however two samples related to a particular research project could not be traced within the freezer indicated as holding this material.

A document review of the establishment's policies and operational procedures was also conducted. This included review of example consent forms, audit schedules, risk assessments, service level agreements and other contracts, and the code of practice for the acquisition, storage and use of human bodily material.

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

HTA standards not met:

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The majority of relevant material sampled can be traced and is effectively supported by a bespoke tissue tracking database. However, samples relating to one research project could not be located within the designated location. This suggests that there are issues of accurate record keeping and storage for that particular set of samples.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE 5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	Although there is an alarm monitoring system for refrigeration and freezer units, this is not subject to routine testing. Staff working under the licence are unaware as to whether the alarm system is functional. Additionally, there are no formal out-of-hours arrangements in the event of freezer breakdown.	**Minor**

Advice

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

No.	Standard	Advice
1	-	Operationally, matters relating to tissue governance are currently managed within a senior technical post with the postholder having a number of additional main responsibilities. Although the DI discharges her own statutory duties appropriately, it is recommended that the establishment review current staffing structure and assess issues of demand and capacity in relation to specific activities under the licence. This is in order to assure itself that these activities can be effectively managed, moving forwards, by an appropriate member of staff.
2	C3	It is advised that periodic refresher training is provided to staff involved in seeking consent so that individuals maintain an awareness, and are kept

		abreast, of regulatory requirements relating to consent.
3	GQ1	The establishment has a local governance framework in place with evidence of Human Tissues Steering Group meetings which focus on matters relating to licensable activities. It is recommended that the establishment embed the work of this Group within established University governance structures, with clear reporting lines.
4	GQ1, GQ5	The DI is advised to develop suitable Service Level Agreements (SLAs), where necessary, for the storage of any remaining relevant material beyond the completion of a research study and/or the defined period for REC approval. These SLAs should include instances where specific instructions may be indicated, such as disposal arrangements.
5	GQ1	The DI is advised to consider implementing a system of signature logs to evidence the reading and understanding of SOPs by staff members. Although existing arrangements are working effectively given the limited scope of material currently held under this licence, this approach may help ensure staff are appropriately trained should activity levels increase in the future.
6	GQ2	Staff undertake regular database audits to routinely check and update the inventory of retained material. However, there are a lack of audits in place for other activities in relation to HTA standards (e.g. audit of the consent process and supporting documentation in use). The DI is advised to extend the scope of audits currently conducted.
7	GQ8	The establishment has a clear risk assessment (RA) process in place. The DI is advised to further extend RAs to include potential risks related to tissue loss, loss of tissue integrity and loss of traceability; for example, to assess the risk of receiving tissue with incomplete or non-conforming consent documentation and actions to be taken in such circumstances.
8	PFE3	The contingency freezer unit maintained within the basement of the School contains a number of additional items stored within the freezer on an *ad hoc* basis. It is recommended that this freezer is kept empty in the event that relevant material needs to be moved to this unit in an emergency. Additionally, the DI is advised to formally risk assess the current situation and determine whether contingency arrangements are sufficient for main freezers holding relevant material.
9	D2	Although the site is recording the reason for disposal, the database does not display this field. The DI is advised to consider that any future system modifications include a field clearly displaying the reason for disposal, where applicable.

Concluding comments

A number of strengths and good practices were identified. For example, although the establishment is currently holding only a limited number of samples under this licence, a number of robust systems have been put in place to ensure traceability. The establishment has developed an effective tissue tracking database detailing movement and storage locations of samples and details of research use. There is an ID tracking system with unique identification numbers generated at the level of individual samples. This facilitates a robust

chain of custody process for the majority of samples stored for individual research projects. The code of practice for the 'acquisition, storage and use of human bodily material for any scheduled purpose' is a wide-ranging and well-constructed core document which clearly defines responsibilities and accountabilities in relation to activities conducted under the licence. This document has been established in consultation with the PABS Human Tissues Steering Group. There is also a suite of risk assessments in place with an appropriate focus on areas of regulatory risk, e.g. unathorised storage, access and use of relevant material. The HTA endorses the concerted efforts of the DI to develop effective lines of communication with all staff working under the licence to ensure that she is kept fully abreast of relevant information relating to licensable activities.

As highlighted above, there are some areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

The HTA requires that the DI addresses the two identified 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 two shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 23 April 2013

Report returned from DI: 2 May 2013

Final report issued: 2 May 2013

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: 03 October 2013

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 in place 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.

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   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.