Site visit inspection report on compliance with HTA minimum standards

Peninsula College of Medicine and Dentistry, Plymouth

HTA licensing number 12103

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 December 2012

Summary of inspection findings

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

Although the HTA found that the Peninsula College of Medicine and Dentistry, Plymouth (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to internal audit and risk assessments.

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

This report refers to the activities carried out by Peninsula College of Medicine and Dentistry, Plymouth. The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004 and has been licensed by the HTA since 2007. This report describes the first routine site visit inspection of the establishment, which took place on 11 December 2012.

The Peninsula College of Medicine and Dentistry, Plymouth, was established in 2002 and currently conducts research focusing on four main themes: Diabetes, Cardiovascular Risk and Ageing; Neuroscience; Health Services Research; and Environment and Human Health. The majority of human tissue samples held by the establishment are stored and used in projects with approval from recognised research ethics committees (RECs). As such they are exempt from the licensing requirements of the Act. Where this was found to be the case, the establishment's systems relating to the storage and use of this material were not assessed.

At the time of the inspection, a small number of slides containing sections of human pancreatic tissue were being held as part of a research project without approval from a recognised REC. These samples were being stored under the authority of this licence and had been supplied to the establishment by the Network for Pancreatic Organ Donors with Diabetes (nPOD), a collaborative type 1 diabetes research project funded by the Juvenile Diabetes Research Foundation (JDRF). nPOD, which is based outside of the UK, supplies researchers with pancreatic and related tissues (spleen, lymph node, peripheral blood) for use in immunological, histological, viral, and metabolic research projects. Peninsula College of Medicine and Dentistry are required to submit an application form to request tissue samples, which is reviewed by nPOD's Tissue Prioritisation Committee. Following approval, samples are distributed to the establishment for research use. A proportion of the stained samples which the establishment has received have been returned to nPOD for digital imaging as part of the collaborative project. Records associated with the transportation of each sample, both receipt and distribution, are retained by the establishment.

The inspection included a review of documentation relevant to the establishment's activities and interviews with key members of staff working under the licence, namely the Professor of Biomolecular and Cellular Science, who is also the Designated Individual, and the Professor of Endocrine Pharmacology. A visual inspection of the premises was also conducted, during which an audit of four samples held in storage was performed. For each sample, storage locations were cross-checked with appropriate records, and related files were reviewed to ensure that they contained all relevant documentation including transportation/delivery records. The samples chosen for the audit were representative of the relevant material currently stored under the licence and included stained and unstained sections of human pancreatic islets stored at room temperature and at -20^{o}C. No discrepancies were found.

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
GQ2 There is a documented system of quality management and audit.	Although the establishment were conducting informal audits concomitant with sample use, a clearly defined schedule of formal, documented audits encompassing licensable activities had not been set out or implemented. Such an approach would bring the establishment in line with HTA's requirements and also the establishment's own SOPs which state that audits will be conducted at least annually.	**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 relating to many of their experimental procedures, these focus primarily on the health and safety of those involved in the activity and do not currently address the risks to the samples themselves (e.g. through storage, distribution or disposal). Acceptable risk levels were not clearly defined, nor were the risk levels that would necessitate implementation of additional control measures.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	Imported material should be procured, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. The consent provisions of the HT Act do not apply if the material has been imported. Nonetheless, the HTA considers it good practice to ensure mechanisms are in place in the source country for obtaining consent, where this is applicable. The DI is advised to review the practical guidance set out in the HTA's code of practice on Import and export of human bodies, body parts and tissue and review whether the establishment's current procedures provide the necessary assurances.
2.	GQ1	The DI is advised to implement a system of formal, minuted governance meetings focusing on licensable activities, in keeping with the approach outlined in SOP 'JBBHTA100/Governance'. The frequency and scope of such meetings should reflect the level of activity under the licence and should be reviewed on a regular basis to ensure they remain appropriate.
3.	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.
4.	GQ3	Although the establishment's existing induction process makes reference to the Human Tissue Act, 2004 and its implications for research involving relevant material, the DI is advised to consider whether the training provided to researchers can be developed further to ensure that staff are aware of the requirements of this piece of legislation. This could include, for example, the use of e-learning tools as part of the induction process.
5.	GQ7	The DI is advised to review the wording of SOPs that deal with adverse event/incident management to ensure that they accurately reflect the requirements of the Human Tissue Act, 2004. References to reporting requirements that relate only to establishments licensed under the Human

		Tissue (Quality and Safety for Human Application) Regulations 2007 should be removed for clarity.
6.	PFE3	The DI is advised to consider the use of additional signage on slide boxes and freezers/cupboards where relevant material is stored to further mitigate the risk of accidental damage or loss of samples held under this licence.
7.	PFE3	Although access to the laboratories, and the premises themselves, is restricted, the DI is advised to consider locking the cupboard and the freezer used to store unstained and fluorescently-labelled material respectively. Such an approach, which is already used for the storage of non-fluorescently stained slides, would standardise the approach taken by the establishment and would help strengthen existing security measures.
8.	D1	The DI is advised to update the establishment's disposal SOP to ensure that it captures the steps to be taken in the event that slides become damaged or broken and require disposal. References to hair and nails should also be amended to clarify the circumstances under which they are designated as relevant material under the Human Tissue Act, 2004.

Concluding comments

The HTA saw several examples of good practice during the course of the inspection.

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. All samples were very clearly labelled with unique identifiers. Storage locations of samples, and details of research use/distribution, were captured in comprehensive spreadsheets which also contained cross-references to entries in laboratory books where additional information about use was recorded.

The establishment has also drafted a number of SOPs for activities that are not currently undertaken by staff working under the licence, but which may be undertaken in the future. This includes a detailed, well-written SOP relating to the consent process. This approach ensures that the establishment is well prepared for future developments in relation to their research activities, and is reflective of a commitment to continuous review and development that was evident during the inspection.

Two areas of practice were identified during the inspection that require improvement, resulting in minor shortfalls. These relate to the establishment's current approach to audit and the requirement for the establishment to conduct and document risk assessments for all licensable activities, such as the storage, use and distribution of relevant material, in addition to their existing Health and Safety risk assessments.

The HTA has given advice to the Designated Individual with respect to some of the establishment's governance and quality systems, mostly around SOPs, governance meetings and staff training. The HTA has also given advice on a couple of aspects of the establishment's storage 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: 10 January 2013

Report returned from DI: 23 January 2013

Final report issued: 25 January 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: 24 January 2014

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

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.

   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.