Site visit inspection report on compliance with HTA minimum standards

Cardiff Metropolitan University

HTA licensing number 12408

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 – 27 August 2015

Summary of inspection findings

The HTA found that Cardiff Metropolitan University (the establishment) did not meet the majority of the HTA's standards. Five major shortfalls were found in relation to consent, governance arrangements and sample traceability. Seven minor shortfalls were identified in relation to the standards for consent, governance and quality systems, transport arrangements and disposal records.

The HTA found the Designated Individual (DI) not to be suitable to continue in the role. An application from the establishment to change the DI was approved by the HTA following the inspection.

The Licence Holder, Licence Holder contact and the premises were found to be suitable in accordance with the requirements of the legislation.

The HTA's regulatory requirements

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

The statutory duties of the DI 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

Cardiff Metropolitan University (the establishment) is licensed under the Human Tissue Act 2004 (HT Act) for storage of relevant material for use for scheduled purposes. This licence applies to the Llandaff Campus (hub site) and the Cyncoed Campus (satellite site).

The establishment has been licensed by the HTA since June 2007. The first HTA site visit inspection of the establishment was conducted in June 2009. This inspection resulted in three conditions being placed on the licence; these related to improvements required to consent information (standard C2), consent training (standard C3), and documented policies and procedures (standard GQ1). The establishment provided evidence to satisfy the HTA that these conditions had been met. Since that time, the DI has changed and the establishment has reviewed a number of policies and procedures relating to the HTA licence.

This report describes the second, routine site visit inspection of the establishment. The inspection timetable was developed in consideration of the establishment's licensing history, activities conducted under the licence and discussions with the DI. The inspection included a visual inspection of areas where relevant material is stored under the licence, interviews with establishment staff and a review of documentation. Although no relevant material was stored at the satellite site at the time of the inspection, the inspection team visited the Cyncoed Campus to inspect the storage of consent documentation relating to relevant material stored at the hub site and to view areas where material may be stored in the future.

The establishment stores relevant material for the scheduled purposes of 'research' and 'education or training relating to human health'.

Research – the majority of samples stored under the establishment's HTA licence are stored for use for research. At the time of the inspection, the establishment was storing samples under the HTA licence in connection with fourteen research projects. Where the establishment does not have evidence that plasma and serum samples have been prepared in a manner confirmed to render them acellular, these samples are considered to be relevant material and are stored under the licence in order to ensure compliance with the HT Act.

The establishment also stores samples which are exempt from the licensing requirements of the HT Act because they are either: confirmed to be acellular and so not considered to be relevant material under the HT Act; or stored for research with approval from a recognised research ethics committee (REC). At the time of the inspection, samples exempt from the licensing requirements of the HT Act were stored for four research projects.

The establishment requires all researchers to notify the DI of the intention to store human samples at the establishment, whether or not the storage is exempt from the licensing requirements of the HT Act. The Persons Designated (PDs)maintain a record of all research projects collecting and/or storing human samples. The establishment requires that researchers obtain approval for use of human samples for research from one of the University's ethics committees, unless they have approval from a recognised REC. Researchers are required to maintain a file containing paper records of key documentation relating to human samples collected, stored or transported to/from the establishment. Files for projects storing samples under the licence are held at the hub site by the Cardiff School of Health Sciences (CSHS) Research and Enterprise Support Office or at the satellite site by the PD for this site.

Staff and students seek consent for the collection, storage and use of samples for research. Consent training is provided by the establishment's Research and Enterprise Services Unit. Completed consent forms are stored in project files. The inspection identified a number of concerns relating to the establishment's consent procedures, documentation and training (see major shortfalls for standards C1 and C3, and minor shortfall for standard C2).

Samples may be received from organisations both within and outside of England, Wales and Northern Ireland. Researchers are required to obtain approval from the DI for samples to be transferred and stored under the licence. The approval process includes checks on agreements with organisations supplying samples to provide assurance that consent has been given in accordance with the regulatory requirements.

The establishment transfers samples to other organisations. Researchers are required to obtain approval from the DI for distribution of samples stored under the licence. The approval process includes checks on agreements with organisations receiving samples to provide assurance that samples will be stored and used in accordance with the consent given.

The establishment requires that records of transport and agreements with third party organisations supplying or receiving samples are stored in project files.

The establishment requires researchers to assign a unique identification code to all human samples to track storage, use, distribution and disposal. Researchers are required to record all samples in an electronic sample inventory for each project, termed an 'Inventory of Human Samples'. The establishment uses a secure, online application for storage and management of controlled databases and documents relating to the licence. Access to these electronic files is controlled by the DI and PDs.

Although the HTA licence allows storage of relevant material under the licence at both the hub and satellite sites, at the time of the inspection all samples stored under the licence for use for research were stored in central facilities at the hub site. These storage facilities are located in secured areas and are under the oversight of the PDs.

Frozen samples are stored in -20°C or -80°C freezers or in vapour-phase liquid nitrogen. There is a -40°C freezer at the Cyncoed Campus that may be used to store samples under the HTA licence in the future. Fresh samples are stored at 4°C in a refrigerated cold room. The freezers and cold room are locked. Storage temperatures of the freezers and cold room are monitored and there is an automated alarm with a notification procedure in the event of deviation from the set acceptable maximum temperature. Liquid nitrogen levels are monitored weekly and filling of the liquid nitrogen tanks is recorded. The establishment has contingency arrangements for storage in the event of equipment failure.

Education and training – the establishment stores relevant material from the deceased and living for use for education and training. At the time of the inspection, the establishment was storing three collections of microscope slides at the hub site for use for education and training.

The establishment does not have documented procedures relating to the acquisition, storage and use of relevant material for education and training (see major shortfall for standard GQ1).

Audit findings – the inspection identified two collections of relevant material that were not recorded as being stored at the establishment and were not subject to the establishment's governance arrangements for the HTA licence (see major shortfall for standard GQ6).

- A collection of 41 buffy coat samples had been stored at the establishment since August 2015 for use for research. Although samples were assigned identification codes and recorded on an inventory held by the researcher, this inventory was not subject to document control and did not contain sufficient details of sample use or disposal. The establishment did not have records of the transport of these samples to the establishment or agreements with the supplying organisation.

- A collection of 53 microscope slides from a commercial supplier had been stored at the establishment since June 2013 for use for education and training. The samples did not have unique identification codes and were not recorded on an inventory.

A further seven collections of uncatalogued samples were identified during the inspection. Six of these collections were acellular samples and one collection was stored for a project with approval from a recognised REC. Although these samples are not subject to the licensing requirements of the HT Act, their transfer to and storage at the establishment outside of local procedures indicates concerning departures from the establishment's governance arrangements.

The inspection team conducted audits for each of the 14 research projects and three teaching collections stored under the licence. This included audits of sample traceability and a sample of records of consent, traceability, disposal and agreements with third parties. In addition to the uncatalogued samples, these audits identified a number of discrepancies (see major shortfalls for C1 and GQ6). These discrepancies were:

- three consent forms that had not been fully completed and so did not provide evidence of consent for the storage and use of samples from these participants;
- one box of 56 samples recorded on the inventory that could not be located in storage;
- one sample that could not be traced to the inventory because the unique identification code on the sample could not be read; and
- one sample that was being stored but was recorded as having been disposed of.

These audits also identified minor discrepancies in the use of the traceability systems for two collections. These findings related to researchers having not updated storage location plans and discrepancies in the format of identification codes written on the samples and recorded on the inventory; however, these discrepancies did not affect sample traceability.

Inspection findings

The HTA found that the establishment did not meet a significant number of the HTA's licensing standards. These shortfalls are considered to largely result from poor governance of activities covered by the licence since the last HTA inspection and following a change of Designated Individual (DI), a change which was originally intended as only an interim measure pending the appointment of a permanent DI.

Due to the range and severity of the shortfalls, the HTA considered the DI not to be suitable to continue in the statutory role and this was discussed at Licence Holder level. Following the inspection, the HTA approved an application from the establishment to change the DI.

The Licence Holder was found to be suitable in accordance with the requirements of HT Act.

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.	The establishment does not have: • a documented policy for seeking consent; or • a standard operating procedure (SOP) detailing the process for seeking consent. The establishment was required to document a consent policy and procedure to meet a condition placed on the licence resulting from the HTA inspection in 2009. The establishment provided evidence to satisfy the HTA that these documents were introduced. However, the establishment subsequently archived these documents. *(Refer to advice item 4)* In addition, the inspection team's audit identified three consent forms that had not been fully completed and therefore did not provide evidence that consent has been given for the storage and use of the samples from these participants. *Prior to the inspection report being issued, the establishment provided evidence that these participants were successfully approached again for their consent ('re-consented').*	**Major**

	Consent forms and participant information sheets for several projects storing samples under the establishment's HTA licence do not provide information that the samples will be stored before being used for research, or stored and used for future research. The establishment cannot provide assurance in accordance with the requirements of the HT Act that participants consented for their samples to be stored.	**Major**
C2 Information about the consent process is provided and in a variety of formats.	The establishment does not have a SOP detailing the information that must be provided to participants when seeking consent. *(Refer to advice item 4)*	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Staff and students at the establishment who seek consent are required to complete training in consent seeking. However, the establishment does not have processes to: • assess the competence of staff and students to seek consent before allowing them to seek consent without supervision; or • provide refresher training to those seeking consent. Although the establishment conducts audits of completed consent forms, there are no audits of the process of seeking consent. Taking into account all of the shortfalls found in relation to seeking and obtaining consent, these findings against HTA standard C3 contribute to a significant risk that consent may continue to not be sought in accordance with the requirements of the HT Act.	**Major**

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 establishment does not have SOPs detailing the processes for: • the acquisition, storage and use of samples for education and training; • researchers obtaining approval from the DI to collect and/or store samples for research; or • the management of records, controlled documents and databases. A number of the establishment's SOPs do not contain sufficient details of procedures. The establishment does not have a formal procedure to notify those working under the licence of when policies and procedures are updated. Several policies and procedures were reviewed shortly before the inspection; however, the establishment could not evidence that staff and students had been made aware of, or received training in, the revised procedures. *(Refer to advice items 6 and 7)*	**Major**
GQ2 There is a documented system of quality management and audit.	The establishment conducts audits of sample traceability and records of consent, transport and disposal. However, since the last HTA inspection, the establishment has revised its audit procedures and no longer requires that issues identified by internal audits are addressed. The establishment cannot provide evidence that actions have been implemented to address the findings raised by internal audits. The establishment's SOP for internal audits does not detail the frequency of audits to be undertaken. *(Refer to advice item 10)*	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	The establishment's policy for working under the HTA licence requires that all staff and students are trained in the procedures that they undertake. However, the establishment does not provide training or support on the requirements of the HT Act, which appears to have contributed to the recent poor governance.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The inspection identified a number of issues with the traceability of samples stored under the HTA licence. *Uncatalogued samples* – two collections of relevant material stored at the establishment were not recorded as being stored at the establishment and were not subject to the establishment's governance arrangements for the HTA licence. Although these samples are stored on HTA-licensed premises, their storage outside of the governance arrangements for the licence indicates significant gaps in the establishment's ability to oversee all of the samples stored under the HTA licence. *Discrepancies in sample traceability* – the inspection team's audits identified a number of discrepancies in sample traceability. These discrepancies related to three different collections of samples stored under the HTA licence, where: • one box of 56 samples could not be located in storage; • one sample could not be traced to the sample inventory; and • one sample being stored was recorded as having been disposed of.	**Major**

GQ7 There are systems to ensure that all adverse events are investigated promptly	The establishment has a procedure for those working under the HTA licence to notify the DI of adverse events specifically resulting in the loss of human samples. However, the establishment does not have a documented policy or procedure to ensure that all adverse events are investigated properly. The importance of addressing this shortfall is illustrated by the inspection findings demonstrating that the establishment has not implemented all of the appropriate corrective and preventative actions following an investigation into concerns raised in 2012 relating to activities conducted under the HTA licence. The establishment's investigation identified weaknesses in several areas, including: audit procedures; training of staff in the requirements of the HT Act; and identification and management of corrective actions. However, the establishment did not implement all of the actions identified to address these three areas. These issues were identified as shortfalls during this inspection and will be addressed through the post-inspection corrective and preventative action processes.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has two overarching risk assessments of the risks associated with undertaking licensed activities. However, these risk assessments are not sufficiently detailed and do not accurately reflect the level of risk posed by the establishment's current practices and procedures. The establishment requires that researchers undertake project-specific risk assessments for research using human samples. However, the establishment does not detail what risk assessments must be completed. The establishment did not have project-specific risk assessments for a number of projects storing samples under the HTA licence. *(Refer to advice item 13)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE4 Systems are in place to protect the quality and integrity of body parts, tissues and cells during transport and delivery to a destination.	For the two collections of relevant material stored under the HTA licence that were not recorded on the establishment's inventory or subject to the establishment's governance arrangements, the establishment did not have: • records of transport; or • risk assessments of the transport of samples.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The establishment's SOP and guidance note for disposal do not detail the records of disposal that must be kept. The establishment does not record the reason for the disposal of samples stored under the HTA licence.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The establishment should review its documentation relating to the HTA licence to ensure that it accurately reflects the consent requirements of the HT Act. The establishment is reminded that obtaining University REC approval for extended storage of samples or use of samples for research outside of the scope of the consent given does not provide a lawful exemption from the consent requirements of the HT Act. If the establishment wishes to store samples for longer than the original consent given, or use samples for research outside of the consent given, then they need to consider how they will obtain further consent from the participants. Where samples are from the living and fully anonymised, the establishment may consider seeking ethical approval from a recognised REC. Information on recognised RECs and the consent requirements of the HT Act can be found in the HTA Code of Practice on research (paragraphs 51-57): www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf.
2.	C1	The establishment is advised to record in its inventories details of consent given for the storage and use of samples. For example, to include details of: • the scope of the consent given for storage and use of samples, such as any restrictions on storage duration and whether consent has been given for genetic analysis; and • the duration of REC approval to ensure that samples are disposed of or stored under the HTA licence upon expiry of REC approval. This will help to ensure that samples are stored in accordance with the requirements of the HT Act and are not stored and/or used outside of the consent given.
3.	C1	The establishment is advised to strengthen its assurance that consent for the storage and use of samples for research is sought in accordance with the regulatory requirements. The establishment may wish to produce a checklist to be used when reviewing documentation provided by third party organisations supplying human samples. This could help to ensure a more consistent approach to the review of documentation for the transfer of samples.
4.	C1/C2	The DI should ensure that all projects requiring consent for the collection, storage and use of samples have documented SOPs detailing the process for seeking consent. These SOPs should include details of who can seek consent and the process of seeking consent, including the information to be given to participants and documentation that must be completed. This will help to provide assurance that consent is obtained in accordance with the requirements of the HT Act and that consent forms are completed in a consistent manner.

5.	C2	The establishment is advised to review the participant information sheets for projects where samples are still being collected to ensure that the contact details provided to participants should they withdraw their consent are for a central contact at the establishment, and not for individual researchers who may leave the establishment whilst the samples are still being stored. The establishment is also advised to include details on participant information sheets of the procedure for participants to follow should they wish to make a complaint about the consent process.
6.	GQ1	The DI should ensure that SOPs cover all procedures relating to the licence. The establishment should review all documented policies and procedures relating to the licence to ensure that they are up to date and contain sufficient details. SOPs should provide a clear and accurate representation of a procedure and be detailed enough to ensure uniformity between staff in undertaking procedures. The DI should ensure that there is a formal procedure to notify staff and students when documents have been updated and, where appropriate, ensure that they receive updated training.
7.	GQ1	The DI should ensure that all samples of relevant material stored for a scheduled purpose are subject to the establishment's governance arrangements in order to ensure compliance with the regulatory requirements of the HT Act. The establishment should ensure that there is a documented procedure detailing the process for staff and students to seek approval from the DI to obtain and store samples under the HTA licence. This will help to ensure that this process is conducted and documented in a consistent manner. The DI is advised that storage of relevant material as part of undergraduate courses may be for the scheduled purpose of research, rather than education or training, if the samples are used for research which intends to generate new knowledge or understanding of the diseases, or the functioning, of the human body. Further information on the scheduled purpose of research can be found in the HTA Code of Practice on research (paragraphs 25-28): www.hta.gov.uk/sites/default/files/Code_of_practice_9_-_Research.pdf. The establishment should contact the HTA for further advice if required.
8.	GQ1	The establishment stores cultured human cells. The DI is advised to document the assessment of whether these cultured human cells are relevant material and therefore subject to the licensing requirements of the HT Act. Samples are considered to be relevant material if they contain any cells that originated in the human body. Further information on the definition of 'relevant material' can be found on the HTA website: www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004. The establishment should contact the HTA for further advice if required.
9.	GQ1	The establishment has formed three committees to help to oversee governance of the HTA licence. The DI is advised to ensure that minutes of the meetings of these committees are documented, including timelines for identified actions. Minutes of meetings should be circulated to relevant staff, including the DI. The DI is also advised to ensure that the HTA committee meetings are held in accordance with the frequency defined in their terms of reference. Where meetings are not held, the DI should be informed and the reason documented.

10.	GQ2	The establishment should ensure that records of audits include details of the audit process, findings and required corrective and preventative actions. Actions should be assigned to an individual and deadlines for completion agreed. The completion of actions should be followed up and documented. The establishment is advised to develop a form to record audits. This will provide a documented audit trail and help to ensure that actions are completed in a timely manner. The establishment may wish to consider undertaking audits of projects shortly after researchers commence collection and storage of samples. This will help to identify and rectify any issues in a timely manner to ensure compliance with the establishment's procedures and requirements of the HT Act.
11.	GQ2	The establishment is advised to ensure that all printed documents relating to the HTA licence are document controlled. This should include, for example, printed sample inventories and storage location plans displayed on storage units. These documents should include the date that the document was printed to ensure that traceability records are up to date.
12.	GQ6	The establishment requires researchers to assign unique identification codes to samples stored under the HTA licence. In order to ensure traceability of all samples, the establishment is advised to ensure that unique identification codes are also assigned to samples within a batch. The establishment is advised to ensure that the format of identification codes recorded on sample inventories match the format used on sample labels. The DI is advised to remind all staff and students of the establishment's requirement for sample location plans and inventories to be maintained.
13.	GQ8	The establishment should review its risk assessments relating to human tissue to ensure that they contain sufficient details of the risks and mitigating actions. In particular, the establishment should review the risks associated with: • storage of samples in fridges and freezers that are not subject to planned preventative maintenance or servicing; • use of temperature monitoring equipment that is not subject to planned preventative maintenance or servicing; • storage of samples in a liquid nitrogen tank that is not connected to an automatic filling system or connected to a temperature / liquid nitrogen level monitoring alarm; and • security of samples stored in a liquid nitrogen tank which is not locked. The establishment should also document what project-specific risk assessments researchers are required to complete and how often these risk assessments must be reviewed. The DI is advised to review project-specific risk assessments relating to the HTA licence to ensure that they contain sufficient details and that appropriate risk mitigating actions have been implemented.

14.	PFE3	The DI is advised to ensure that all electronic documents containing participant information are stored on access-controlled systems to ensure confidentiality of participants is maintained and this information is appropriately backed-up. The DI is also advised to consider creating back-up copies of completed consent forms for which the establishment has only single paper copies. The establishment may wish to create electronic copies of consent forms and store these on their access-controlled electronic system. This will help to ensure that records of consent are maintained.
15.	PFE3	The DI is advised to ensure that the temperature alarming arrangements for fridges and freezers are documented, including the temperature trigger points for the alarm. The establishment is advised to periodically, manually trigger the temperature alarms to ensure that they are operating as expected. The establishment is advised to review the form used to record filling of the liquid nitrogen tanks to include a specific column for the liquid nitrogen tank used to store samples under the licence.
16.	PFE3	The establishment is advised to review documented procedures detailing contingency storage arrangements to reflect that the contingency -80°C freezer is no longer kept empty. The DI is advised to keep under review the contingency arrangement for -80°C storage to ensure that it remains appropriate if the number of stored samples continues to increase.
17.	N/A	The PDs at the establishment undertake numerous roles to help oversee activities conducted under the HTA licence. The establishment is advised to ensure that the PDs have sufficient time within their roles to perform the tasks required of them by the establishment's procedures relating to the HTA licence. This will assist the DI in ensuring that he has sufficient oversight of the HTA licence and that the corrective and preventative actions required to address the shortfalls identified by this inspection are completed in a timely manner.

Concluding comments

This report outlines the second HTA site visit inspection of Cardiff Metropolitan University. Although the HTA identified a number of shortfalls, there were areas of good practice observed during the inspection. The establishment has introduced an electronic system to help with the control of documents and databases relating to the HTA licence. The CSHS Research and Enterprise Support Office provides good oversight of the storage of paper records relating to the licence, including completed consent forms.

The PDs demonstrated a good knowledge of the requirements of the HT Act and the HTA Codes of Practice. They undertake key roles at the establishment to help oversee the activities conducted under the HTA licence. They have worked hard to try to ensure compliance with the HT Act. The PD at the hub site has received external training in auditing procedures and practices, and has worked closely with the PD at the satellite site to conduct a wide range of audits relating to the HTA licence. The HTA has given advice to the establishment to further support the PDs in their roles. The PDs and Licence Holder contact demonstrated a willingness to ensure compliance with the HT Act.

The establishment has revised a number of procedures relating to the HTA licence since the last HTA inspection. There are a number of areas of practice that require improvement, including five major shortfalls and seven minor shortfalls. A number of shortfalls identified during the inspection related to poor governance of activities covered by the HTA licence. 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 found the DI not to be suitable to continue in the statutory role. The HTA approved an application from the establishment to change the DI shortly after the inspection.

The HTA will work with the establishment and the new DI to help them to develop a corrective and preventative action (CAPA) plan to address the shortfalls (refer to Appendix 2 for the timeframes within which to complete actions). The HTA will 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 by the licence but requires corrective and preventative actions to be implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 25 September 2015

Report returned from DI: 8 October 2015

Final report issued: 9 October 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: 25 January 2016

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.

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: 26 April 2016