Site visit inspection report on compliance with HTA minimum standards

Bangor University

HTA licensing number 12546

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

13-15 May 2014

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 Bangor University (the establishment) had met the majority of the HTA standards, two minor shortfalls were identified in relation to consent training (Consent standard, C3) and standard operating procedures (Governance and Quality Systems standard, GQ1).

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Bangor University operates under a hub-satellite arrangement and has been licensed under an HTA Anatomy sector licence since 2009. This report describes the first routine site visit inspection of the establishment under licence number 12546. The establishment was previously licensed and inspected under an HTA Research licence (number 12448); there were no outstanding shortfalls or conditions against the licence.

The College of Health and Behavioural Sciences at Bangor University includes the following Schools: Medical Sciences, Psychology, Healthcare Sciences, and Sport, Health and Exercise Science. Donated specimens are used within these schools for the purpose of education and training of undergraduate and postgraduate students enrolled on courses such as: Medical Sciences, Health Sciences, Psychology, Nursing, Midwifery, and Diagnostic Radiology. Approximately 500 students per academic year are taught anatomy and neuroanatomy modules using these donated specimens. The establishment also organises an international summer school which is taught by university staff, and utilises the anatomy teaching facilities. To date, specimens for these and other courses have been imported from a US based tissue supplier. Licensable research activities within the university include projects within the School of Psychology and School of Sport, Health and Exercise Science. These projects are approved by the local university ethics committee and in many cases also include approval by recognised research ethics committees.

Bangor University does not receive donated bodies directly. The bequeathal process is undertaken by another HTA licensed premises, for which the consent procedures have been reviewed previously by the HTA and have been demonstrated to comply with the HTA Code of Practice for Consent. Prosected material is supplied to Bangor University under the terms of a service level agreement. These prosections and then stored under the Bangor University licence. Other licensed holdings include a collection of bones and potted specimens. There is an inventory of donated material at each site, and systems are in place to record the movement of specimens between the hub and satellite premises. Procedures are also in place to record off site transfer to other HTA licensed premises for loan or maintenance purposes.

Teaching facilities include a number of multi-disciplinary rooms, together with a specific anatomy/neuroanatomy teaching facility, which includes two downdraft tables for dissection purposes.

The inspection included a review of documentation relevant to the establishment's activities, a visual inspection of the hub and satellite premises, and interviews with key members of staff including: the Designated Individual, who is a Lecturer in Clinical Anatomy; and Persons Designated including a Lecturer in Nursing; a Senior Lecturer in Physiology; a Lecturer in Physical Chemistry; and a Professor of Clinical Neuroscience and Neuropsychology. The advice and guidance provided to the establishment at the last Research sector inspection had been considered and evidence that it had been acted upon was reviewed during this inspection.

A traceability audit was conducted across a range of specimens including; one anatomical prosection, one brain specimen, four potted specimens, and numerous skeletal specimens. The identity and storage location of each item was cross-referenced with the establishment's records. Traceability was maintained and no discrepancies were identified in the accompanying documentation.

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.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Regarding research activities at the establishment, there is currently no standard operating procedure (SOP) in place detailing the consent seeking process. Staff and students receive consent training as part of the research ethics course, however there was no evidence that this training includes the consent requirements of the Human Tissue Act, or records to demonstrate that training was up to date. See *Advice*, item 2.	**Minor**

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 has developed a set of SOPs for licensable activities (standard C3 excepted), however many could be considered policy statements and do not describe procedures associated with an activity, or do so in sufficient detail. For example, SOP BU003 concerning the storage of human tissue contains no procedural detail. See *Advice*, item 3.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The import and export of relevant material is not licensable under the Human Tissue Act. However, the storage and use of bodies or body parts for education or training relating to human health or for anatomical examination is licensable. With reference to Code of Practice 4 Anatomical Examination, imported material should be obtained, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. The DI is advised to seek assurance from US suppliers of human tissue that consent is in place for the purpose to which the tissue is subsequently used.
2.	C3	Staff seeking consent should undergo suitable training. Training should include the requirements of the Human Tissue Act 2004, and include reference to Code of Practice 1 Consent, and where applicable Code of Practice 9 Research. Attendance at consent training and periodic refresher training should be recorded, and a list of trained staff maintained.
3.	GQ1	SOPs should be a clear and accurate representation of an existing procedure or process, ideally in a step wise fashion to enable any member of staff to follow the procedure to completion. Appropriate staff should be responsible for developing SOPs for their respective procedures, with review and sign of conducted by the DI or another suitably authorised individual or group.
4.	GQ1	Governance meetings are held to discuss licensable activities. The DI is advised to ensure that minutes from the HTA Liaison Group meetings include matters arising from previous minutes, and that actions assigned to staff include a timescale for completion. This will facilitate tracking of ongoing actions. The DI may also wish to consider increasing the frequency of these meetings, particularly considering that licensable activities are conducted over a number of sites.
5.	GQ1	Students are presented with a talk on the expected standards of behaviour when working with human tissue and a code of conduct which must be signed in

		advance of courses and entry to facilities storing human material. The DI is advised to ensure these procedures are rolled out to students at all satellite sites, and may also wish to reference the General Medical Council's guidance regarding the use of photographic images. The DI is also advised to include reference to the form and requirement for its completion in SOP BU006 'taking images of specimens'.
6.	GQ2	The DI is advised to amend wording in the Quality Manual concerning Public Display. The establishment's current licence authorises the storage of relevant material for use in a scheduled purpose, including Public Display, but does not permit the activity of public display itself. The DI is advised to remove reference to procedures for the public display of human material.
7.	GQ2	The DI is also advised to review Admin Policies '002' and '003', since the frequency of document review is inconsistently defined (annually or biennially).
8.	GQ2 and GQ4	There is a documented system of audit; however the DI should assure himself that the frequency of these audits, as defined by the establishment's SOP, is adhered to. The DI is advised that audits could usefully include items on long-term loan, and the accompanying records, for completeness.
9.	GQ5	A coding and records system facilitates traceability. The DI is advised however to assure himself that release and receipt procedures are fully documented to maintain traceability, and that staff are aware of the procedure. The DI is also advised to reinforce that staff complete all applicable fields of the 'loans and transfers forms'. Each site currently has a separate inventory of their respective holdings. The DI may wish to consider a single centralised database to record all material held across hub and satellite premises, which may simplify oversight and audit of licensable holdings.
10.	GQ6	There are systems in place to investigate adverse events; however there is currently some inconsistency in the forms used to report such incidents. The establishment's adverse events policy references a new form currently in development but not yet in use. The DI is advised to finalise the reporting procedure and standardise the use of this form across all sites. This may simplify audit and facilitate trend analysis of adverse events.
11.	GQ7	The establishment has a risk assessment procedure in place, with an emphasis placed on general health and safety. The DI is advised to formalise the risk assessments specific to human tissue, including potential risks such as loss of traceability, loss of tissue, the risk of receiving tissue without appropriate consent documentation, and the actions to be taken in such circumstances.
12.	D2	The establishment has a disposal SOP in place, however there is currently some inconsistency across sites regarding what disposal details are recorded. The DI is advised to review the SOP to ensure that it details sufficiently the requirement to record both the method and reason for disposal, and details the procedure for updating the respective tissue inventory.

Concluding comments

The establishment is managed by an experienced team of staff. It was evident during the inspection that importance is placed on respect and dignity of the deceased, and procedures are in place to safeguard the integrity and security of donated material.

The student induction procedure includes a talk on the expected standards of behaviour and includes an Ethics Health and Safety Agreement form that must be acknowledged prior to admittance to the dissection room. This agreement emphasises the privilege of being able to study human anatomy as part of their training, and that regulations are strictly adhered to.

The establishment benefits from having a Human Tissue Liaison Group, which facilitates oversight and discussion of licensable activities. Audit procedures at the establishment include an external peer audit conducted by the DI of another HTA licensed anatomy establishment.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to the format and improvements required to individual SOPs, and to the content of a consent training programme.

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: 09 June 2014

Report returned from DI: 23 June 2014

Final report issued: 03 July 2014

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: 3 March 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
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 • Independent interpreters are available when appropriate • Information is available in suitable formats
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 licensable activities • 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 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 bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom

GQ6 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)

GQ7 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 • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • 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
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
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 environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
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 transportation • Records of transportation and delivery • Records are kept of transfer 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.