Site visit inspection report on compliance with HTA minimum standards

University of Ulster

HTA licensing number 12064

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**

29 September – 1 October 2015

Summary of inspection findings

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

The University of Ulster (the establishment) was found to have met all HTA standards.

The only previous inspection of this establishment took place in 2008. Since that date, the identity of the DI has changed and another satellite establishment, the Clinical Translational Research & Innovation Centre (C-TRIC), based in Londonderry, has been added to the licence.

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 (the Act). 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

This report refers to the activities carried out by the University of Ulster (the establishment). The establishment currently stores various types of relevant material, including urine and faecal samples, white and red blood cells, whole blood, saliva, buccal swabs and other cellular material, for the scheduled purposes under the Human Tissue Act 2004 of 'education or training relating to human health', 'quality assurance' and, principally, 'research in connection with disorders, or the functioning, of the human body'. Specifically, nutritional, neurological, endocrinological, oncological and sports science research is carried out at the three sites covered by the HTA licence.

The hub site is based at the University's Coleraine campus, with satellite sites at the Jordanstown campus and the Clinical Translational Research & Innovation Centre (C-TRIC) site at the Altnagelvin Area Hospital in Londonderry.

Governance procedures and documentation have been standardised for use across all sites, with only local variation where required. Storage is within monitored, alarmed freezers at either -80°C or -20°C, within the vapour phase of liquid nitrogen in a monitored and alarmed cryostore, or in locked cabinets at ambient temperature, depending on the nature of the samples being stored. All freezers are serviced and calibrated annually, at which time the alarm system is tested. Real-time monitoring of all frozen storage is accessible by a web-based software package, which also allows access to historical records.

All studies carried out by the establishment go through a local (University) or national (NRES) ethics approval process, with study documentation being reviewed by peers and an ethics 'filter committee' before being submitted for full approval**.**

Consent is sought by researchers either in face-to-face meetings with study subjects or by telephone or email communication. Research staff are only permitted to seek consent after they have completed specific training on consent provided as part of induction training managed by the University's research governance department. Consent seeking follows a defined standard operating procedure (SOP), and participants have the opportunity to ask questions and are provided with the option to withdraw consent at any time. They are provided with a Participant Information Leaflet, specific to each study, which follows a standardised layout and contains information about the purpose of the study, the selection criteria for participants, the right to withdraw consent, what the study involves for the participant and the risks and benefits of taking part. The documentation also covers confidentiality and details where enduring consent, for use of samples in other studies, may be sought.

If ethics approval requires it, there is a defined cooling-off period between the consent discussion and the obtaining of consent.

When samples have been obtained, each is assigned a unique sample number, related to each study, by the electronic software program used for tracking and labelling. A label is generated, which includes information relating to the study, and sample type, as well as the unique participant identifier. Sample details are entered into the study log book and the location of samples, in freezers or lockable storage cabinets, are recorded in sample maps, which are held in electronic and paper format. Any movement of a sample is recorded within the study log and sample map, to ensure traceability at all times. If samples are being transferred outside the establishment for analysis, a Material Transfer Agreement is entered into and traceability is maintained by use of various transfer forms, courier records and emails confirming receipt.

At the end of a study, unless enduring consent has been obtained, samples are disposed of following a defined procedure, which is compliant with regulatory requirements and differs only slightly at each site. Disposal forms part of the discussions carried out as part of the initial consent-seeking procedure, and is referred to, where appropriate, in the participant information documentation.

This was the establishment's second HTA inspection. It comprised a visit to each of the sites, a visual inspection of the clinical areas where consent is taken and the storage facilities, review of governance and record documentation and interviews with key staff.

During the visual inspection, an audit of traceability was carried out:

- At the Jordanstown satellite
    - Two samples were located within the storage freezer and their location and label details compared against those recorded within the sample map and study log book. The corresponding consent documentation was located, by use of the unique participant identification number, and was reviewed.
    - One further consent form was located and the corresponding sample traced through the sample map to its location within the storage freezer.
    - Details of one set of samples which had been disposed of were located within the sample map and the corresponding disposal forms and records reviewed.

- At the Coleraine campus
    - Two samples were located within the freezer, and details traced back through electronic and paper records, to the related consent documentation.
    - Another consent form was located and details of three related sample aliquots were selected from the study log. The locations of these were located on the sample map and then that recorded location confirmed within the storage freezer.
    - Records of two samples located within the vapour phase liquid nitrogen cryostore were accessed and the storage location within the cryostore compared with that recorded.

- At the C-TRIC satellite
    - Samples from two participants were selected by reference to the study sample map. These were then located within the storage cupboard and the label details were compared with the identifiers recorded in study documentation. The related consent documentation was then retrieved using the unique participant identifiers.
    - For two further samples located within the storage freezer, the same procedure as that carried out at Coleraine was followed. These samples were part of a National Research Ethics Committee approved study and therefore did not fall under the licence. However as no licensable material was being held in the freezer at the time of the inspection, these samples were used to demonstrate the traceability systems in place.

In all cases, traceability was demonstrated and no discrepancies in documentation were found.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to consider the wording of the SOP governing the seeking of consent (SOP 001) when the document is next reviewed. The SOP refers to information being given to study participants “orally, if appropriate”. This does not reflect either the content of training given to consent seekers, or the practices carried out by staff seeking consent, which always involves information necessary to ensure informed consent being given to the participant verbally, as well as in writing, before consent is taken.
2.	GQ1	The DI is advised to consider the wording of SOP 002, “Applying for ethical approval to undertake category D research” and in particular the context within which the term “relevant material” is used, which suggests that human tissue samples which are not stored are not “relevant material”. The document should make it clear when samples which are obtained and analysed immediately are “relevant material” as defined by the Human Tissue Act 2004, but do not fall under the HTA licence as they are not stored. The DI is advised to ensure that, if the term “relevant material” is used in the same context within other governance documentation, that reference is corrected to minimise the risk of confusion of staff.
3.	GQ7	The DI is advised to review SOP 009 (“Adverse events”), which includes references to the reporting of certain categories of adverse event to the HTA. There is currently no mandatory requirement to report adverse incidents to the HTA but the DI is reminded that the HTA can be contacted where appropriate; for example, for advice or when it is felt that the Authority should be made aware.
4.	GQ8	The DI is advised to consider amending the format of the generic risk assessment of the HTA-licensed activity to ensure it reflects risks affected by differences in procedure or infrastructure at each site. The HTA suggests that the DI may consider using the site-specific risk assessment used at the C-TRIC satellite as a model in drafting any amended risk assessment. By considering site-specific risks, where these differ, the DI will help to ensure that governance documentation meets the needs of staff carrying out activities at each site. The DI is also advised to include the risk assessment of HTA activities within the

		overarching quality management system, to ensure that it is regularly reviewed.
5.	PFE5	The DI is advised to receive copies of all records of routine maintenance of storage equipment, in order to be made aware of any recurring maintenance issues. This may help in the on-going assessment of the risk of equipment failure.

Concluding comments

The HTA saw various examples of good practice during the inspection. All staff involved in research involving human tissue must undertake an HTA induction course, presented by the University's research governance department and refreshed on a three-yearly basis. This places a strong emphasis on consent procedures and introduces staff to governance documentation specific to the licensed activity. The regulatory framework is also covered in detail as part of initial induction training.

Researchers are provided with comprehensive training on consent, with guidance and template documentation to support them in drafting the consent and other documentation required to prepare an application for project approval. A system of peer review of project-specific documentation is in place and project documentation is further reviewed by a 'filter committee' to ensure it meets the requirements of the Act, before being considered by either the local or national ethics committee.

At least once during the life of each project, an audit is carried out by the DI and staff from the research governance department. This audit reviews training records of staff, all project documentation and sample records and also tests traceability. Corrective actions are put in place where necessary.

The HTA found that staff interviewed seemed to value the governance systems put in place to ensure the safe and ethical use of relevant material in accordance with the Act and HTA's licensing standards; the close working relationship and good communication between the DI, Persons Designated and staff in the research governance department appears to help foster this attitude.

The HTA has given advice to the Designated Individual with respect to some elements of documentation and risk assessments.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 14 October 2015

Report returned from DI: 23 October 2015

Final report issued: 23 October 2015

Appendix 1: HTA standards

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

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management

committees, agendas and minutes

- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.