Site visit inspection report on compliance with HTA minimum standards

Oakfield House, School of Social and Community Medicine

HTA licensing number 12512

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**

4-5 May 2016

Summary of inspection findings

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

Oakfield House, School of Social and Community Medicine, Bristol (the establishment) was found to have met all HTA standards.

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

This report describes the second routine site visit of Oakfield House, School of Social and Community Medicine, University of Bristol (the establishment). The previous inspection took place in 2013. Since the previous inspection, two satellite sites were added to the licensing arrangements: Research Floor Level 7 (RFLS) and Langford House. RFLS is located at the Bristol Royal Infirmary. The Langford House site was not inspected on this occasion because it was inspected in October 2015 as part of licence 12248, when it was in the process of moving to become re-licensed as a satellite site of this licence. The University of Bristol has a University Research Governance Team which supports research undertaken at the University and keeps a list of all research projects involving human participants, their tissue and/or data and their approval status.

The inspection comprised of a visual inspection of storage areas where human tissue is stored. This included freezers, fridges, a -20^0C cold store, a cryostore containing liquid nitrogen storage vessels and samples stored at room temperature. A review of governance arrangements, documented procedures and records of traceability, and interviews with the Designated Individual and key staff, were also undertaken.

The establishment has a variety of research projects; all samples stored are samples from living donors. The majority of samples stored at Oakfield House, are from the Avon Longitudinal Study of Parents and Children (ALSPAC). The ALSPAC study is an established study which follows over 14,000 pregnant women who were recruited and followed up in the early 1990s. The health and development of the children continues to be followed and, in many cases, their children may also be involved in the study. The clinic for the ALSPAC study is located at Oakfield House where the study participants are interviewed, tests undertaken and samples taken. Samples are barcoded. Participants are provided with information packs and leaflets about the study before they arrive at the clinic. Consent is sought, face-to-face, by trained fieldworkers, working to a documented standard operating procedure (SOP).Consent documentation is always checked and signed off by a second member of staff.

The majority of work done at RFLS is under NHS REC approval. The Bristol Biobank has received approval from a recognised research ethics committee to operate as a Research Tissue Bank. These samples are collected from donors using biobank specific consent forms and information provided to volunteers. Samples where consent is still valid for future research may also be deposited into the biobank from projects where NHS REC approval has expired. Cardiovascular tissue paraffin blocks are also stored at RFLS.

Each sample is labelled with a unique identifier and a code is used to link it to each research collection. The unique identifier is used to ensure the confidentiality of volunteers. Access to the database records containing patient identifiable information is also restricted. There are plans to use a barcoding system for samples in the Bristol Biobank.

The establishment has formalised processes in place and Material Transfer Agreements (MTAs) are completed before samples are sent to other locations or exported. This process was reviewed during the inspection as part of the audit trail.

Storage of relevant material takes place in -80ºC, -20º C freezers, a -20º C coldstore, a cryostore or at room temperature. All samples are located in secure, restricted access areas. Access to sample storage areas in Oakfield House is restricted with swipe cards to the main areas and by either keypad lock or key lock to individual store rooms and the cold store. This level of access ensures that only a limited number of identified staff have access to samples. A proprietary temperature monitoring system is used to monitor storage temperatures. Freezers, cold stores and cryostores that store human tissue operate on a 24-hour alarm system. The alarm operates through a network connection and is backed up by a telephone call out system. Staff participate in a rota and are contacted on a dedicated phone in case of an emergency. There is a system for regular testing of alarms. There is a contingency plan for storage of material in case of a break down or power failure.

A traceability audit was carried out at Oakfield House and RFLS. Nineteen samples from various research projects were selected at random from the freezers, coldstore, cryostore and room storage. The storage locations and sample identifiers were traced to the computer records for RFLS and followed in the opposite direction for Oakfield house (computer records to freezer). The relevant consent forms were also reviewed. No discrepancies were found.

An audit trail was also done on some research samples exported to a research laboratory in the United States. The request for tissue samples, review and approval of the request by the governance committee and DI, consent forms, the relevant MTA, list of samples sent and storage location within Oakfield House and shipment records were checked. No discrepancies were found.

Disposal of relevant material takes place by a defined process following University human tissue waste procedures and disposal is recorded within records or databases as appropriate.

Inspection findings

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

Compliance with HTA standards

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.	C1	RFLS Templates and consent forms are available. There is also a thorough training programme for staff who seek consent. Research undertaken at the University includes projects which have NHS REC approval as well as those which only have local approval. The DI is advised to formalise the process of making all researchers, including new members of research teams, aware of these templates and consent forms and inform them of the need to be trained in seeking consent before they seek consent from donors. By doing so, the DI will help to assure herself that consent procedures remain robust and help to ensure that appropriate and valid consent is in place for collections received into the Bristol Biobank.
2.	GQ8	Oakfield House and RFLS The establishment has a large collection of samples and has assessed the risks relating to tissue loss, traceability and tissue damage. The DI is advised to also assess the risks of continued storage and use of samples after consent has been withdrawn. By doing so, the DI will strengthen procedures and assure herself that steps are taken to mitigate the risk of storage and use of samples after consent has been withdrawn.

Concluding comments

The HTA saw various examples of strengths and good practice during the inspection:

- The environment in the clinic, information provided to donors, training of staff, and overall governance of the ALSPAC study promotes a comfortable environment for volunteers, which is evidenced by the continued engagement of all volunteers including the children of the original participants.

- The establishment has a thorough documented procedure for audits of licensable activities. Annual audits are carried out by the University's Human Tissue Working Group, with Designated Individuals across other licenses, which helps promote shared learning with staff.

- The documented checks of the alarm call-out systems for the fridge and freezer alarms are robust.

- There is an effective system of incident reporting. Incidents are reviewed and appropriate actions taken and documented.

- Signs are placed on freezers which have empty shelves. This is helpful as staff can easily identify which freezers can be used for storage and transfer samples to those freezers in the event of an emergency.

The HTA has given advice to the Designated Individual with respect to making staff aware of consent procedures 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: 24 May 2016

Report returned from DI: 29 May 2016

Final report issued: 10 June 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.