**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**

**27 June 2013**

## Summary of inspection findings

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

Oakfield House, School of Social and Community Medicine was found to have met all of the 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 first site visit inspection of Oakfield House, School of Social and Community Medicine, University of Bristol on the 27 June 2013. The ALSPAC laboratory is the main laboratory which is housed at Oakfield House and was set up to manage samples from the Avon Longitudinal Study of Parents and Children (ALSPAC) in the early 1990's. The ALSPAC study recruited over 14,000 pregnant women and has followed the health and development of the children since then. The laboratory also manages sample collections for other cohort studies, some with NHS ethical approval and some held under licence.

Participants are seen in the clinics where trained Field Workers, usually Research Nurses, obtain consent for research and including obtaining samples. When a participant attends the clinic the Field Worker will update the electronic system to show that the participant has arrived and will update the system to show how many blood tubes have been taken. This system is then used by the ALSPAC laboratory to inform them when samples are ready to be collected from the clinic. The ALSPAC laboratory are also able to check the system to ensure that consent has been given, before any samples are processed. The samples are processed and the buffy coat layer is then banked and stored temporarily in the -80$^0$C and -20$^0$C freezers within the ALSPAC laboratory before they are moved to the permanent storage which is located in the basement of Oakfield House. The freezers in the ALSPAC laboratory are not linked to any monitoring system, however the establishment has undertaken a formal risk assessment, where risk mitigation is achieved through regular maintenance as well as recording of temperatures twice weekly.

The permanent storage, where samples are transferred for long term storage, comprises of: two freezer rooms containing -80$^0$C freezers, -30$^0$C and -20$^0$C freezers, one Cryostore with liquid Nitrogen tanks, one walk-in -20$^0$C cold room and room temperature storage. All storage areas are monitored both manually as well as via a monitoring system which is linked to the University's security department that will contact the relevant person in the event of an alarm on a 24 hour basis. As the permanent storage is in the basement the alarm is connected to the main ALSPAC laboratory to enable the laboratory team to hear the alarm. The storage areas hold several types of tissue samples from various cohort studies that have been carried out over the years. Each storage area has a visual map which highlights freezers/liquid nitrogen tanks that contain existing holding samples, ethically approved study samples and material that falls outside of the HT Act 2004 as it is not relevant material.

The inspection comprised interviews with the DI and key members of establishment staff. The inspection also involved a visual inspection of the storage areas, traceability audits and document review. Both forward and reverse audits were carried out on four tissue samples, which included placental blocks and slides, blood spots and urine. This involved locating samples from storage and tracing back to the electronic system as well as locating a sample in storage on the system and checking its physical location. All samples were fully traceable and there were no discrepancies found.

### Inspection findings

The HTA found the Designated Individual 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 |
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| 1. | C1 | Potential research participants are asked for their consent to store their tissue for research including DNA analysis. In its current format, the consent form does not include specific provision to enable the consent seeker to record that the participant had given their consent for DNA analysis as part of the intended research. The DI is advised to consider amending the consent form to include a separate clause with regards to DNA analysis.This will allow participants to 'initial/sign' their consent to DNA analysis and enable them to be clear about the consent they have provided. This is especially important as many participants are involved in the long term studies and may subsequently find it difficult to recall the full range of research activities for which they originally gave their consent. |

## Concluding comments

The DI and establishment staff have worked hard to ensure a high level oversight of licensable activities. Several examples of good practice were noted during the site visit inspection. The establishment stores several thousand tissue samples, a proportion of which are existing holdings and stored under the licence. All of the tissue that is stored on the premises has been appropriately catalogued. The establishment operates a HTA Working Group which provides oversight of all HTA licences. The HTA Working Group is responsible for coordinating and carrying out independent audits of the research licence once a year and the laboratory team also carry out HTA audits regularly. All audits are carried out against the HTA standards and CAPAs are set and addressed accordingly.

The ALSPAC Executive Committee is responsible for granting permission for all research proposals, to ensure that only scientifically valid studies are approved before human tissue can be used in research. The establishment have adopted best practice and use mirror banking to ensure that all tissue collected from a participant is divided amongst storage locations so that in the event of mechanical freezer failure, not all of the tissue will be lost.

Consent training is provided by the University and the DI delivers HT Act 2004 training to new starters. The completion of the participant consent form is carefully checked by members of staff prior to the participant's departure from the clinic. Any incomplete information or errors are checked. The establishment uses a piece of electronic software which is used to scan the consent forms to check for missing information or any discrepancies.

**Report sent to DI for factual accuracy: 22 July 2013**

**Report returned from DI: 29 July 2013**

**Final report issued: 29 July 2013**

## 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** |
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| **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<br>• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose<br>• 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<br>• 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<br>• 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<br>• Agreements with third parties contain appropriate information<br>• Independent interpreters are available when appropriate<br>• Information is available in suitable formats, appropriate to the situation<br>• 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<br>• Evidence of suitable training of staff involved in seeking consent<br>• Records demonstrate up-to-date staff training<br>• Competency is assessed and maintained |

| Governance and quality system standards |
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| **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<br>• Appropriate risk management systems are in place<br>• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes<br>• 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).<br>• Schedule of audits<br>• 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<br>• Orientation and induction programmes<br>• Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training<br>• Training and reference manuals<br>• 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<br>• Regular audit of record content to check for completeness, legibility and accuracy<br>• Back-up / recovery facility in the event of loss of records<br>• 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

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| contamination<br>• 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<br>• Contingency plans are in place in case of failure in storage area<br>• Critical storage conditions are monitored and recorded<br>• System to deal with emergencies on 24 hour basis<br>• 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<br>• A system is in place to ensure that traceability of relevant material is maintained during transport<br>• Records of transportation and delivery<br>• Records are kept of any agreements with recipients of relevant material<br>• 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<br>• Users have access to instructions for equipment and receive training in use and maintenance where appropriate<br>• Staff aware of how to report an equipment problem<br>• Contingency plan for equipment failure |

| Disposal Standards |
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| **D1 There is a clear and sensitive policy for disposing of human organs and tissue** |
| • Documented disposal policy<br>• Policy is made available to the public<br>• 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<br>• 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.