Site visit inspection report on compliance with HTA minimum standards

Orchid Cellmark Ltd

HTA licensing number 12575

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**

8 October 2014

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.

Orchid Cellmark Ltd (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 (the HT 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 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 refers to the activities carried out by Orchid Cellmark Ltd. The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose, and has been licensed by the HTA since January 2011. The report describes the first routine site visit inspection of the establishment, which took place on 8 October 2014.

Orchid Cellmark Ltd is based in the Abingdon Business Park and specialises in genotyping and DNA analysis in the fields of forensic science, paternity testing and agricultural genotyping. Forensic work is conducted on behalf of police forces across England and Wales. The establishment is also contracted the Home Office to provide DNA profiling in immigration cases and it collects and stores human tissue samples from members of staff for the purposes of performance assessment and quality assurance. The storage of each of these types of samples from living persons is exempt from the licensing requirements of the Human Tissue Act. Therefore, the systems associated with their collection, storage and use were not formally reviewed during this inspection.

Instead, the inspection focused on storage of tissue samples from deceased persons used for the paternity testing work undertaken by the organisation. The establishment is accredited by the Ministry of Justice as a body that may carry out parentage tests as directed by the civil courts in England and Wales under section 20 of the Family Law Reform Act 1969. It also undertakes paternity testing on behalf of families requiring this service to settle claims on the deceased's estate. The establishment receives a wide variety of relevant material in relation to this service, including buccal swabs, blood, hair, bone, skin and muscle biopsies. Samples can come from both the living and the deceased. Where samples are taken from the living, robust procedures are in place to confirm the identity of the donor. Samples from the deceased are typically supplied by hospitals, although personal effects may be sent in for analysis by the families concerned. In all cases, samples are receipted into the establishment according to well-defined procedures before being stored in secure facilities that are temperature controlled, monitored and alarmed. DNA testing is not performed until signed consent forms have been returned to the organisation. The consent forms sent out to interested parties include provision for capturing the family's wishes regarding the return or disposal of samples post-analysis.

The inspection included interviews with key members of staff working under the licence, including the Quality Director, who is also the Designated Individual (DI), the Identification Operations Manager and the ID Operations Interpretation Manager. A review of documentation relevant to the establishment's activities and a visual inspection of the premises where licensable activities are carried out were also conducted as part of the inspection.

An audit of three samples held in storage was performed. Storage locations were cross-checked with electronic records, and donor files were reviewed to ensure that they contained all relevant documentation, including consent forms. No discrepancies were found.

Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings were reviewed by HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the Act.

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	The DI is advised to review the wording of the executor consent form to ensure that it is consistent with its current usage. For example, if the purpose of this form is to establish whether a person has given consent, or has made a decision not to consent, to DNA analysis prior to death, then the wording of the form should be amended accordingly. If, however, the purpose of this form is to seek consent from somebody other than a person in a qualifying relationship to the deceased, then provision should be made within the form to establish whether the individual satisfies the requirements of a nominated representative, as defined by Section 4, Part 1, of the Human Tissue Act, 2004. The DI is also advised to update the next-of-kin consent form to include the statement that appears on the current executor consent form regarding the provision of false information.
2.	GQ1	The DI is advised to implement a system of assurance to ensure that where relevant material is removed from the deceased for use for a scheduled purpose, this activity is only undertaken by individuals acting under the authority of an

		appropriate HTA licence. The DI is also reminded that consent is needed for the removal of tissue from the deceased for use for a scheduled purpose and the establishment's approach to the seeking of consent should reflect this. If the deceased has not indicated their consent (or refusal) to this activity, consent is needed from a person in the hierarchy of qualifying relationships. Unlike the consent for DNA analysis, consent for removal of relevant material from the deceased for a scheduled purpose should be obtained from the person ranked highest in the hierarchy.
3.	GQ2	Although the establishment has recently conducted a very comprehensive audit of working practices against HTA standards, the DI is advised to review the frequency and scope of such audits going forward. In particular, the DI should consider including regular horizontal audits of holdings and records as part of the establishment's schedule of audits.
4.	GQ4	The DI is advised to update the form entitled 'Request for STR profiling' (reference number: FRP0002) to include a mandatory field for 'return to' information. Although this information was consistently captured on the documents reviewed during the inspection, a lack of a defined field on the form may lead to this information being inadvertently omitted.
5.	GQ8	The DI is advised to expand the scope of the establishment's existing risk assessments to include activities such as the taking of consent and disposal of samples. This will help ensure that the risks associated with all aspects of the work being conducted under the authority of the establishment's HTA licence are appropriately considered and documented.

Concluding comments

The HTA saw numerous examples of good practice during the course of the inspection.

There is a clear commitment on the part of the establishment to the development and implementation of robust governance and quality systems to support the work taking place under the authority of their licence and throughout the organisation. The establishment has sought and received accreditation from a number of external bodies, and currently operates a quality management system (QMS) that complies with the requirements of, for example, ISO9001, ISO17025, ISO14001, ISO27001 and ISO17020. Consequently, features of the establishment's QMS, such as document control, audits, and non-conformance reporting were well-managed.

The establishment has a comprehensive and well thought-out programme of staff training, which extends from staff induction through to annual appraisal and continuous professional development. It also makes effective use of IT systems to ensure that staff are aware of, and adhere to, the most up-to-date procedures. In keeping with this, there is a strong commitment to continuous improvement throughout the organisation. The establishment has recently set up an HTA Governance Committee to ensure appropriate oversight of the work taking place under the authority of the licence, and implemented a number of changes to working practices to further enhance the establishment's traceability and distribution procedures. It has a very robust approach to the follow up of audit findings, and clearly gives careful consideration to advice and guidance offered during such exercises.

No shortfalls were identified during the course of the inspection. The HTA has, however, given advice to the Designated Individual with respect to a number of the establishment's

procedures, documents and working practices with a view to helping the organization further develop its working practices.

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

Report sent to DI for factual accuracy: 30 October 2014

Report returned from DI: 5 November 2014

Final report issued: 10 December 2014

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.