Site visit inspection report on compliance with HTA minimum standards

LGC Ltd

HTA licensing number 12600

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 June 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.

LGC Ltd (the establishment) was found to have met all HTA standards.

Advice has been offered to the establishment with regards to the documentation updates, audits, risk assessments and freezer monitoring.

Particular examples of 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

The establishment has been licensed since 2012 and this routine inspection was its first site-visit inspection to assess whether it is meeting the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's licence application information, and pre-inspection discussions with the DI. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

The establishment provides genotyping services for various national and international customers who provide samples for testing. DNA is not relevant material under the Human Tissue Act 2004 (HT Act) and therefore a storage licence from the HTA is not required to store DNA pending analysis. The establishment however can also receive tissues and/or cells from its customers and will undertake DNA extraction prior to genotyping. A storage licence is required by the establishment because tissues and cells (relevant material) are considered by the HTA to be being stored prior to the extraction of DNA.

Whether the samples received by the establishment require DNA extraction or arrive as extracted DNA, they are booked into the establishment's electronic laboratory information system (LIMS) upon arrival. The LIMS is used to track the samples and attributes either a unique identification code to each sample or, in the case of already extracted and plated DNA, a unique code to each sample plate. Each code references a plate map with individual sample identifiers contained within.

Consent for research is not sought by establishment staff as it is sought by the various suppliers of the samples. The establishment does however have a number of check steps so that the DI may assure himself that the samples which are received have been obtained following an informed consent process.

When supplying samples, the establishment's customers must complete a sample form containing high level details regarding the samples. On this form is a Human Tissue Act 2004 declaration where customers confirm whether or not samples have been obtained following an informed consent procedure and that this consent allows the proposed analysis. In addition, the establishment requests a blank consent form used when seeking consent for obtaining and using the samples to again verify that the proposed analysis is in accordance with the consent given.

The sample detail form and the blank consent form are stored on the establishment's electronic file management system under a folder specific to a customer's project. Prior to extracting any DNA or commencing any analysis of the samples, staff verify that the sample detail form has been returned to the establishment and is correctly completed.

The establishment stores samples awaiting DNA extraction and extracted DNA in a large freezer. The freezer is monitored and linked to an alarm system which would contact establishment staff should there be a malfunction out of hours.

During the inspection a traceability audit was undertaken. Three racks of samples awaiting extraction and two racks of extracted DNA were selected at random from storage. Details including the number of samples, sample layout and identifiers on the racks were cross checked between the samples and the establishment's LIMS. No anomalies were found.

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 check steps which establishment staff perform are not currently reflected in the establishment's written procedures. During the inspection staff were able to demonstrate the checks performed on the sample information sheet and the blank consent form however no reference to these checks is documented. The DI is advised to amend the 'Extraction Project Set Up and Generation of Project' – LGC-EX013 and the 'Receipt of Samples for Extraction' – LGC-001 standard operating procedures (SOPs) to include details of the checks on the forms that are performed by establishment staff.
2.	C1	The DI is advised to develop a means of informing the establishment's customers of the need to contact the establishment should any of the sample donors wish to withdraw their consent to the research. This will help mitigate the risk of donor's samples proceeding any further through the analysis pipeline if they have changed their mind about study participation and it is possible to

		withdraw their consent.
3.	GQ2	The establishment is still developing its audit schedule and has developed an audit plan for the coming year. The DI is advised to include process/witness audits within the schedule whereby establishment staff performing a particular task are audited against the relevant SOP. This will help to assure the DI that both staff are following the SOPs and also that the SOPs remain fit for purpose and reflect the actual procedure being undertaken.
4.	GQ8	The establishment has risk assessments in place and although they mainly relate to business continuity or Health and Safety, some do address the risks to the stored samples, such as lack of security or freezer failure. The DI is advised to expand on the range of risk assessments in place so that the risks posed to the samples are more fully addressed. These risks include but are not limited to: risk of loss of traceability, risk of receiving unconsented samples, risk of sample loss through sample handling in the laboratory.
5.	PFE3	Although the establishment's storage freezer is alarmed and temperature monitored, the establishment does not review the recorded temperature plots. The DI is advised to initiate a program by which, at suitable timeframes, the temperature plots from the freezer monitoring system are reviewed. This may help to identify a potential failure of the freezer system before it occurs should for example, staff notice a trend of slowly rising temperatures over a period of time. In addition, the DI is advised to periodically and manually trigger the freezer's temperature alarm to ensure that it is activating as expected. This manual challenge of the alarm system did take place when the new facilities were occupied but has not occurred since.

Concluding comments

Good practices were observed during the inspection, some examples of which are included below.

The establishment maintains particularly detailed training logs for establishment staff reflecting the training and competency sign off for each member of staff. This helps the DI in ensuring that suitably trained staff undertake work under the licence.

The establishment has also implemented a good system of control for paper versions of SOPs throughout the establishment. Folders of paper copies of SOPs are located throughout the establishment meaning that the Quality Manager can track, update or withdraw documents easily knowing where all copies are located. Additionally, responsibility has been devolved to members of staff to take charge of the SOP folders with these members of staff reporting to the quality manager details of any changes or updates which may be necessary to the documents.

The HTA has given advice to the Designated Individual with respect to documentation, audits, risk assessments and freezer monitoring.

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

Report sent to DI for factual accuracy: 2 July 2014

Report returned from DI: 2 July 2014

Final report issued: 29 July 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.