Site visit inspection report on compliance with HTA minimum standards

Imanova Ltd

HTA licensing number 12587

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**

18 November 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.

Imanova Ltd (the establishment) was found to have met all HTA standards. Advice has been provided to the DI in several areas to aid continual improvement and support good practice.

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

Imanova Ltd is a centre for imaging sciences and their application to biomarker and early drug development. The establishment works with academic and commercial organisations on pre-clinical and clinical research projects, involving the collection of samples from patients such as blood, urine, saliva and faeces and the analysis of mostly neurological tissue samples obtained from approved tissue banks. The vast majority of the research conducted by the establishment falls under recognised Research Ethics Committee approval and is therefore outside of the HTA licence. Samples for projects without recognised Research Ethics Committee approval are received, on average, one or two times per year, but may be stored for up to a year depending on the research project. Although some samples such as blood, saliva and urine may be collected onsite, consent for use of the samples in research is taken prior to this, offsite, by appropriately trained staff in accordance with the agreed study design. A rigorous check is then made on the consent obtained for all samples used by the establishment.

Imanova Ltd have held an HTA licence since August 2011 and this was the first HTA site visit inspection. A routine inspection of the establishment was carried out comprising a visual inspection of the two wards areas where samples are collected, the PET scan facility and the processing laboratories on the ground floor and level one, where samples are also stored; an audit of stored samples; document review; and interviews with four key members of staff. At

the time of the inspection, no human tissue was held under the authority of the HTA licence and therefore an audit was conducted on samples being stored for projects with current recognised Research Ethics Committee, which was verified. Two blood samples from living patients were selected at random from the -20°C freezer, one was found to have an incorrect date of sampling on the label compared with the corresponding paperwork (see advice section). Two slides of brain sections received from a HTA licensed brain bank were selected at random from the -80°C freezer, records were checked and no anomalies found.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. This DI has been given advice below in respect of these roles.

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.	GQ1, D2	The establishment's licensed processes are documented, but some of the SOPs would benefit from a little more detail and explanation as to why a task should be carried out in a specified way. This would help ensure staff have a wider understanding of the requirements of the Human Tissue Act 2004. For example, the document on disposal describes the process well but does not explain why waste should be separated and in particular the sensitivities around disposal of tissue from the deceased and the document for freezer failure should provide more detail for the action to be taken by staff on call.
2.	GQ3	All staff receive induction training and, in addition, staff dealing with human tissue receive training about the HTA and the Human Tissue Act 2004 when they start employment and as refresher training. Whilst this training is very good, it is suggested that it is more explicit about who the DI is and that he should be notified of any issues relating to the licence and such issues need not follow the normal lines of escalation to ensure he is notified in a timely fashion.
3.	GQ4	The establishment has clear records for all its samples; those in long-term storage are recorded electronically and the records are backed-up regularly. Some of the samples collected, processed and dispatched within days, or occasionally weeks, are only recorded on paper records. The DI is advised to consider a way of backing-up these records to prevent the risk of loss of this information.
4.	GQ6	During the traceability audit conducted by the inspection team, one sample out of four was found to have an incorrect sampling date on the label. The date recorded was when the sampling should have occurred, but it was delayed and happened a day later. Such delays happen on an occasional basis and are unavoidable. Staff were able to demonstrate the link between the dates on their records, so the sample remained traceable, however the DI is advised to review

		and risk assess this process to prevent misleading labelling.
5.	GQ8	There are a number of risk assessments which relate to the health and safety of staff and an annual risk assessment that covers broader areas, however the format of this is similar to an audit and it is therefore suggested to make this a clearer assessment of the risk identified and the actions taken to mitigate the risk or reduce the risk to acceptable levels. The DI should also ensure that all the risks related to the tissues and cells, such as loss or damage of a sample, loss of traceability, transportation of samples, are all considered.
6.	N/A	The DI and the Corporate licence holder contact (CLHC) roles are undertaken by the same person, as when applying for the licence there was only one candidate suitable to fulfil these roles. The DI is advised to consider transferring one of these roles to another suitable member of staff, to ensure sufficient oversight of licensable activities should either member of staff be absent.

Concluding comments

There were no shortfalls identified during the inspection, however the HTA has given advice to the Designated Individual with respect to supplementary details in SOPs, staff training, risk assessments, back up of paper records and ensuring accurate dates on sample labels. The DI has also been asked to consider transferring one of his roles to another member of staff, so that the DI and CLHC roles are fulfilled by different people.

Several areas of good practice were identified during the inspection. Staff use a checklist to systematically review the consent documents for the samples they receive to ensure that consent has been obtained and the consent given encompasses the use of the samples for the research project in question. The establishment uses a unique numbering system to ensure patient confidentiality and has a good system of recording sample locations even when they have temporarily moved location during freezer failure, or maintenance. There are clear signs on the freezers providing instruction on what to do in the event of freezer failure and these signs are document controlled. Overall the establishment staff showed a good level of understanding of HTA requirements and a commitment to continuous improvement.

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

Report sent to DI for factual accuracy: 15 December 2014

Report returned from DI: 22 December 2014

Final report issued: 30 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

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.