Inspection report on compliance with HTA licensing standards

Inspection date/s: Sera Laboratories International Ltd t/a BioIVT: **10 March 2020**
Clinical Trials Laboratory Services (CTLS Limited): **11 and 12 August 2021**

Sera Laboratories International Ltd t/a BioIVT
HTA licensing number 12699

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
Hub site **Sera Laboratories International Ltd t/a BioIVT**	Licensed	Not licensed
Satellite site **Clinical Trials Laboratory Services (CTLS Limited)**	Licensed	Not licensed

Summary of assessment findings

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

Sera Laboratories LTD t/a BioIVT (the establishment) had one minor shortfall in relation to Governance and quality systems (risk assessment).

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfall identified.

Compliance with HTA standards

Minor Shortfall

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	Risks relating to storing or using human tissue after consent withdrawal are not covered in the establishment's risk assessments.	**Minor**

Advice
The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	C1(d)	The agreements that the establishment has with clients state that human material supplied to them may be used *in vivo* in animals; however, the information used to support the seeking of consent covers research in general terms and does not include this as a possibility. For consent to be valid, the individual should understand the nature and purpose of what is being proposed which includes how the tissue will be used. To ensure transparency on areas of public concern, for example where research is known or is likely to involve the use of human tissue in animals, this should be covered in the information used to support the consent process.
2.	GQ6(a)	To demonstrate transparency in how risk ratings are determined, the DI is advised to consider including the contributing impact and likelihood data in the documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.

Background
The establishment has been licensed by the HTA since December 2019. This was the first assessment of the establishment. The DI under the licence is responsible for the Quality Assurance and Business Support for the establishment. The Corporate Licence Holder

contact (CLHc) is the General Manager. The Persons Designated (PDs) on the licence are the Donor Centre Manager and Logistics and Documentation Manager.

Since the licence was issued in 2019, there has been a change to the DI under the licence and a change of premises for the satellite site.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The establishment hub was inspected on March 2020. Due to the national response to the COVID-19 pandemic, the satellite site was assessed virtually in August 2021. The Regulation Manager covered the following areas during the assessment:

Standards assessed against during inspection

All 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing staff training, adverse events, incidents and audits were also reviewed.

Visual inspection

A visual inspection was conducted by the inspection team at the hub site and the satellite site was inspected through the use of a virtual tour of the premises.

Meetings with establishment staff

The assessment included discussions with the CLH contact, the DI, PDs under the licence, Operations Manager and a Principal Investigator.

Report sent to DI for factual accuracy: 24 August 2021

Report returned from DI: 06 September 2021

Final report issued: 20 September 2021

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Virtual Regulatory Assessment Report.

Date: 10 January 2022

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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 routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.