Inspection report on compliance with HTA licensing standards
Inspection date: **23 February 2022**

Source Bioscience Limited
HTA licensing number 12344

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
Source Bioscience Limited	Licensed	Not licensed

Summary of inspection findings

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

Although the HTA found that Source Bioscience ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards relating to risk assessments.

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 shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments are reviewed regularly.	There is no current provision for regular review of the risk assessment document that has been recently developed.	**Minor**
c) Staff can access risk assessments and are made aware of risks during training.	Establishment staff have not yet had access to the risk assessment document that has been recently developed.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	C2(a)	Although the establishment is not directly seeking consent for research, there may be plans to do this in the future. The DI is advised to review the HTA's standards and guidance on consent training (C2 standards) ahead of any planned implementation.
2.	GQ2(b)	Following an audit, the establishment aims to carry out a 'close-out' meeting to agree any corrective and preventative actions. During the review of one of the audits, it was found that a close-out meeting did not take place and no rationale was provided as to why this was the case. The DI is advised to consider how greater consistency can be demonstrated and that the rationale for not having a close-out meeting is documented.
3.	GQ2(b)	Auditing of disposal is only documented if the establishment finds any issues. In order to improve the evidenced demonstration that the establishment is in compliance with our standards and is meeting the requirements of its own systems, the DI is advised that audits focussing on disposal are documented regardless of whether discrepancies are identified or not.
4.	GQ5(a)	The DI may wish to consider adding details about the types of incidents relevant to HTA activities that should be flagged internally.
5.	PFE2(c)	Although there is a robust, web-based temperature monitoring system in place, the DI is advised to consider regular testing to challenge the alarm to ensure the call-out system is working as expected.
6.	PFE2(c)	The DI is advised to consider adding information on the freezer doors to highlight that they contain human tissue. This may help to prevent sample mix-ups, ensure full traceability and ensure that staff are aware of the need to manage such samples in line with the regulatory requirements.

7.	PFE2(d)	The DI is advised to consider placing information on the freezer door which sets out where samples can be transferred to during a freezer failure. This may help to guide staff on where tissue can safely re-located, particularly those who are new or who do not routinely work with human tissue.

Background

Source Bioscience Limited is a Contract Research Organisation, that undertakes research on behalf of clients ('sponsor organisations'). The establishment also provides histopathology and genetics services to the NHS.

The establishment has been licensed by the HTA since June 2007. This was the second inspection of the establishment; the most recent previous inspection took place in May 2011.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Inspector covered the following areas during the inspection:

Standards assessed against during inspection

Standards C1(b),(d),(e) and (f) and C2(a)-(c) were not assessed as applicable as the establishment does not seek consent directly. Of the 47 standards, 40 standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to, standard operating procedures for licensable activities, key policies, study audits including an audit against HTA standards, meeting minutes, staff training records, traceability records, temperature montitoring data and incidents.

Visual inspection

As this was a virtual regulatory assessment, there was no visual inspection of the premises; however, a virtual tour of the storage areas (accommodating -80 and -20 degrees Celsius freezers) was carried out.

Audit of records

No traceability audit carried out; however, a review of the establishment’s audits was undertaken as part of the assessment, reviewing key areas such as sample receipt, processing, storage and disposal. There were no issues identified.

Meetings with establishment staff

A round table discussion was carried out with establishment staff and included the DI, Project Managers (including a Person Designated), the Quality Assurance Manager and a Senior Quality Assurance Officer.

Report sent to DI for factual accuracy: 11 March 2022

Report returned from DI: 25 March 2022 (no comments)

Final report issued: 28 March 2022

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: 12 April 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 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 inspection.

   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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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