Inspection report on compliance with HTA licensing standards
Inspection dates: **25 and 27 March 2025 (site visits)**

GSK

HTA licensing number 12202

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 **GSK (Stevenage)**	Licensed	Not licensed
Satellite site **GSK (Addenbrooke's Hospital)**	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 GSK ('the establishment') was found to have met the majority of HTA standards, one minor shortfall was identified against Traceability standards. This was in relation to inaccurate traceability records identified during a sample traceability audit.

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 during the inspection.

Compliance with HTA standards

Minor shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	During a tissue traceability audit, a donor sample was identified from the sample database and traced through to its storage location. Although the sample tube was correctly barcoded and linked to the donor selected, it was noted that another donor number was associated with the same bar code. This meant that the same barcode had been assigned to two different donors on the sample database due to a transcription error; however, the sample tubes were correctly labelled. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment had drafted an updated standard operating procedure for seeking consent at the satellite site following a review of its procedures for its tissue bank activities at the satellite site. To strengthen the procedure further, the DI should consider including pictures of correctly completed consent form fields. This may help to support staff in how to complete a consent form correctly and in line with documented procedures.
2.	GQ4(b)	The establishment operates a tissue bank at the hub site, in collaboration with a local hospital that collects surplus tissue from patients following surgical resections. The hospital uses the establishment's consent template and information sheet to seek consent from patients and provides confirmation that consent is in place via email to the establishment. There is also an agreement between the establishment and local hospital which confirms that it is the responsibility of the hospital to seek consent for research. The DI should consider appropriate back-up arrangements for information that forms part of the establishment's consent records.
3.	T1(b)	The establishment enters sample traceability information onto a spreadsheet, which is then transcribed onto the sample database. The DI should incorporate a system that prevents transcriptions errors that occur during manual entry of information.
4.	PFE1(b)	The blood donation unit, based at the hub site, has a 'lock box' outside the unit where blood samples are stored for a few hours after collection from donors. The lock box is in an area that is accessible to all staff. To increase the security of the lock box, the DI is advised to consider changing the code on a regular basis.

Background

The establishment is a global biopharma company which specialises in vaccine development to prevent and treat disease. The establishment operates under a hub and satellite licensing arrangement, located in Stevenage and Cambridge. It hosts three ethically approved research tissue banks, which collect and store samples from healthy volunteers and also receive tissue following surgical resections.

Description of inspection activities undertaken

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

Standards assessed against during inspection

All 47 HTA standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the inspection roundtable meetings which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, sample database, temperature monitoring data, incidents and agreements.

Visual inspection

The hub and satellite sites were visited as part of the inspection, including the Blood Donation Unit located at the hub site. The inspection team met with two consent-trained phlebotomists who were responsible for seeking consent and taking blood.

A traceability audit of samples stored in the tissue banks was undertaken. This also included a review of records relating to consent, such as agreements with third party suppliers and consent templates.

Day 1- Hub site

A traceability audit of seven samples was undertaken. The samples were identified from their storage locations and tracked through to the sample database. The consent form template and agreement associated with the samples were linked to the database. No discrepancies were identified.
A records audit associated with sample disposal was undertaken. There was a clear process involving approval of tissue to be disposed.

An audit trail of tissue from a deceased person was carried out. As this sample was no longer stored, the audit focussed on traceability records only. The due diligence checks around consent were clearly documented.

Day 2- Satellite site

A traceability audit of a sample obtained from a third-party supplier was undertaken. The sample was identified from storage location and tracked through to the sample database. The consent form template was linked with the sample along with the agreement. No discrepancies were identified.

An audit of four donors that had been recruited to a historical research tissue bank was undertaken. A traceability audit was performed by identifying one of the donors from the sample database through to the storage location. The consent form was reviewed and there were no discrepancies. When the stored sample was located, it was found that the donor number was linked to a sample bar code of another donor. A transcription error had occurred which led to two donors sharing the same sample bar code on the database. The samples from each donor were correctly labelled with the correct bar code and there was no sample mix-up (see Minor shortfall, T1(a)).

Three further samples obtained from third party suppliers were identified from the sample database and tracked through to the storage locations. The consent form template was linked to each sample. No discrepancies were identified.

Audit of records

Audit reports undertaken by the establishment were reviewed at the facility on the day of the audit as part of the inspection process.

Meetings with establishment staff

Roundtable discussions were carried out with establishment during the two-day site-visit. Staff included the DI, Persons Designated (PDs), the Quality Assurance Team and the Human Tissue Re-use team.

Report sent to DI for factual accuracy: 28 April 2025

Report returned from DI: 13 May 2025 (with comments)

Final report issued: 2 June 2025

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.