Inspection report on compliance with HTA licensing standards

Inspection dates: 16 June (virtual regulatory assessment) & 27 June (site visit) 2025

UCB Biopharma UK

HTA licensing number 12504

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
UCB Biopharma UK	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 UCB Biopharma UK ('the establishment') had met the majority of the HTA's standards, six minor shortfalls were found against standards for Consent, Governance and quality systems, and Traceability. These related to consent training, documented policies and procedures, risk assessment and maintaining a register of donated materials.

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.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice	The establishment's documented consent procedures for the healthy donor programme were inconsistent. Current practice was to use an electronic consent platform whereas two documents (UCB Phlebotomy Policy & Human Tissues Quality Manual) referred to staff meeting with donors to seek consent. Furthermore, at the time of the assessment there was no documented procedure for reconsenting donors.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	Healthy donors provided autonomous consent through an electronic platform managed by a subcontractor. However, staff from the subcontractor routinely engaged with donors regarding consent and reviewed completed consent forms. At the time of the assessment, there was no evidence that these staff had received consent training that addressed the requirements of the HT Act and the HTA's Codes of Practice.	**Minor**

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Some SOPs documented in the HTA Policies and Procedures Manual lacked sufficient clarity and procedural detail to enable new staff to follow a procedure from beginning to end. Examples included, but were not limited to, procedures relating to sample labelling, recording of sample receipt, use and disposal on the register of donated material, cleaning and decontamination, and records management.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.	The establishment did not have a policy or documented agreement regarding the retention of consent forms completed as part of the healthy donor programme.	**Minor**
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.	The establishment's risk assessments did not include storage or use of human tissue following the withdrawal of consent.	**Minor**
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to	The procedures documented in the HTA Policies and Procedures Manual permitted a period of up to 10 days from sample receipt or collection during which the registered location of the donated material was not adequately maintained. In	**Minor**

which any material was put; when and where the material was transferred, and to whom.	addition, at the time of the inspection, there was no system in place to record any time limits associated with consent.	

Advice

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

Number	Standard	Advice
1.	C1(c)	A third party supplier provided the establishment with material from deceased donors. To strengthen assurances, the DI is advised to confirm in any relevant agreements that appropriate consent has been given in accordance with the hierarchy of qualifying relationships set out in section 27(4) of the Human Tissue Act 2004.
2.	GQ3(b)	The establishment employed a 'buddy' system to support new laboratory staff. The DI is advised to formally document and maintain a record of this system to strengthen the induction process.
3.	GQ6(c)	The establishment recorded and managed risks within a centralised risk register rather than through individual risk assessments. Although staff had access to this register, its size and complexity made it difficult to navigate and understand. To strengthen staff training and awareness, the DI is advised to explore more user-friendly formats for presenting key risk information relating to HTA-licensable activities.

Background

UCB Biopharma UK is a division of a global biopharmaceutical company focused on discovering and developing treatments for neurological and immunological conditions as well as rare diseases. The establishment collects and stores samples from healthy donors and procures tissue from both living and deceased donors through research tissue banks and commercial providers. The establishment has been licensed by the HTA since

November 2007. This was the third routine inspection of the establishment; the most recent inspection was a site visit inspection and took place in March 2018. Since the previous inspection, there have been some significant changes to the personnel named on the licence including the Designated Individual in July 2018 and the Corporate Licence Holder contact (CLHc) in May 2023 and March 2025.

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 licensing standards were assessed (standards published 3 April 2017). The assessment consisted of a virtual regulatory assessment (focused on standards under C1, C2 and GQ1-GQ6) followed by a site visit assessment (focused on standards under T1, T2 and PFE1-PFE3).

Review of governance documentation

A number of documents were reviewed during the virtual regulatory assessment roundtable meetings which included, but were not limited to, standard operating procedures and risk assessments for licensable activities, key policies, meeting minutes, consent form templates, participant information sheets, temperature monitoring data, incident reports, disposal records and agreements. Consent for the healthy donor programme was managed by a subcontractor and obtained using an electronic platform.

Visual inspection

The visual inspection conducted during the site visit included a tour of areas housing room temperature, -20°C, -80°C, and liquid nitrogen storage, as well as the goods-in mailroom, phlebotomy room, and laboratories. A traceability audit of 15 samples was undertaken during the site visit. The audit included a review of records relating to consent, such as completed consent forms, agreements with third party suppliers and consent templates. The samples included material from both deceased and living donors, sourced from various suppliers, encompassing different types of material and

different storage locations. Nine samples were identified from purchase orders, phlebotomy appointments and database entries and traced forward to their respective locations. Five samples had been used-up and were no longer in storage. The consent agreement for another of these samples specified a 10-year limitation. Although the sample was imported and had been fully used-up before exceeding the time limit, the establishment did not have a system in place to record and monitor such consent-related limitations. Evidence of consent was reviewed for the remaining eight samples. The four samples recorded as being in storage were successfully located, with no discrepancies identified.

An additional six samples were located in storage and traced back through the sample database to the corresponding consent documentation. No discrepancies were identified regarding the recorded storage locations. Completed consent forms, or where applicable, documented due diligence checks relating to consent, were available. One of the samples originated from a deceased donor and was supplied by a research tissue bank with approval from a Health Research Authority Research Ethics Committee. The consent template and associated agreement were reviewed (*Advice*, item 1). No discrepancies were identified.

Audit of records

Records reviewed as part of the virtual assessment included those pertaining to staff training, cleaning and reports for audits undertaken by the establishment.

Meetings with establishment staff

Roundtable discussions were carried out with establishment staff during the virtual assessment and during the site visit. Staff included the DI, Persons Designated (PDs), the Quality & Auditing Team, Facilities Team, as well as the Learning & Training Team, representatives from the subcontractor that manages the healthy donor programme, and a phlebotomist.

Report sent to DI for factual accuracy: 9 July 2025

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 23 July 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.