Inspection report on compliance with HTA licensing standards
Inspection date: **16 September (remote) and 17 September (site visit) 2024**

The Discovery Centre (AstraZeneca)
12109

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
The Discovery Centre (Hub site)	Licensed	Not licensed
Joint AZ Functional Genomics Screening Laboratory (Satellite)	Licensed	Not licensed
AstraZeneca Granta Park (Satellite)	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.

The Discovery Centre (AstraZeneca) ('the establishment') was found to have met all of the HTA's standards.

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The establishment has a dedicated quality team that conducts a range of audits, with actions followed up at the end of the audit process. One of the larger research groups working with human tissue had developed a self-assessment form to enable them to conduct their own audits. As this audit approach is not part of a formalised process, the DI should consider how information arising from the self-assessment process could be used by the quality team.
2.	GQ6(a)	The establishment had risk assessments in place which focus on risks relevant to storage of human tissue. The majority of risks had control measures documented clearly; however, some areas were less detailed than others. To strengthen assurances on risk management and improve consistency of approach, the DI is advised to review the level of detail provided for control measures and make amendments accordingly.
3.	PFE2(d)	The establishment has a comprehensive document called *'Management of Unexpected Temperature Excursion and Planned Defrosts of CTUs at The DISC'* which provides steps to be followed if there is a critical storage

		failure. The DI is advised to consider providing an up-to-date copy of this document in key areas which could be affected by a critical storage failure so that staff can access the procedure easily.

Background

The establishment is a pharmaceutical company, which also operates a biobank that has approval from a recognised Research Ethics Committee (REC). The Biobank receives surgical tissues, blood, plasma, serum, urine, other body fluids and cells; all surplus to diagnostic and therapeutic requirements. The Biobank team centrally co-ordinate the receipt and distribution of all samples, internally and externally. The Biobank stores material from living and deceased donors.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager 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 assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, temperature monitoring data and incident reports.

Visual inspection

The hub site was visited as part of the inspection. The satellite sites were not storing any human tissue at the time of the inspection and were not visited.

A traceability audit of samples stored in the Biobank was undertaken. This also included a review of the establishment's process for ensuring that appropriate agreements and consent could be evidenced for all samples included in the traceability audit.

Freezer 1

A 'forward' traceability audit of a sample from the sample database to its storage location was undertaken. No discrepancies were identified.

A 'reverse' traceability audit of a sample from its storage location to the sample database was undertaken. No discrepancies were identified.

Freezer 2

Two samples were tracked from their storage locations to the sample database. The samples were fully traceable, and no discrepancies were identified.

Ambient storage

Two formalin-fixed paraffin embedded (FFPE) tissue blocks were tracked from their storage locations to the sample database. The samples were fully traceable, and no discrepancies were identified.

Liquid Nitrogen

Two samples were tracked from the sample database to their storage locations. The samples were fully traceable, and no discrepancies were identified.

Release of tissue from the Biobank

22 FFPE tissue blocks were tracked from the sample database to their storage locations at a research laboratory at the establishment. The samples were fully traceable, and no discrepancies were identified.

Material from deceased donors

A sample was tracked from the sample database to its storage location. The sample was fully traceable, and no discrepancies were identified.

Audit of records

Audit reports between 2023 and 2024 were reviewed as part of the inspection process.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Person Designated (PD) and Quality Assurance Team.

Report sent to DI for factual accuracy: 4 October 2024

Report returned from DI: 7 October 2024

Final report issued: 11 October 2024

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.