Inspection report on compliance with HTA licensing standards
Inspection date: **15 December 2021**

Alderley Park

HTA licensing number 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
Hub site **Alderley Park**	Licensed	Not licensed
Satellite site **AstraZeneca**	Licensed	Not licensed
Satellite site **Babraham Building B623**	Licensed	Not licensed

Satellite site **Darwin Building**	Licensed	Not licensed
Satellite site **Joint AZ CRUK Functional Genomics Centre**	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 Alderley Park ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found – one against a standard for Governance and quality systems (risk assessments), and another against a standard for Premises, facilities and equipment (sample storage conditions).

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

Standard	**Inspection findings**	**Level of shortfall**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

c) Staff can access risk assessments and are made aware of risks during training.	Access to risk assessments is restricted to senior management staff.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	A recent internal audit at one of the satellite sites identified the following: • The storage units were not locked, in line with establishment expectations. • One of the -80°C freezers was not linked to the continuous temperature-monitoring unit.	**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.	GQ2(b)	Audit findings and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording audit findings, discussions about the audit, who is responsible for follow-up actions and the timeframes for completing these.

2.	GQ5(b)	Adverse events and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording adverse event findings, discussions about the adverse event, root cause analysis and resulting corrective and preventative actions.
3.	PFE1(a)	Although assessments of each premises had been carried out when the satellite sites were added to the licence, the DI is advised to review and update these to ensure that each remains fit for purpose.
4.	PFE2(c)	One storage room at the hub site and six rooms at three of the satellite sites contain formalin-fixed paraffin wax-embedded blocks and sections at ambient temperature; these rooms are not temperature monitored. Excessive or prolonged raised temperatures in these rooms may lead to biomarker degradation. The DI is advised to assess the risks of these current arrangements and consider the effects that storage temperature deviations could have on the integrity of the samples stored.
5.	PFE3(a)	The DI is advised to ensure that all storage unit maintenance and probe calibration contracts are kept up to date. This will help to provide assurances that equipment remains suitable for use.

Background

Alderley Park contains one NHS Research Ethics Committee (REC)-approved, HTA-licensed Research Tissue Bank (RTB) containing relevant material from living and deceased donors. This is based at the hub site. It receives relevant material from suppliers, collaborators and clinical trials worldwide as well as from the AstraZeneca Biobanks in Sweden and the USA. Additionally, the RTB stores relevant material from expired UK Ethics Committee Authority (UKECA) approved or REC project-specific approved studies. This RTB provides relevant material predominantly to research groups within the organisation.

The establishment has been licensed by the HTA since June 2007. This was the second inspection of the establishment; the last one took place in October 2010.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in 2015 and the current Corporate Licence Holder contact (CLHc) was registered with the HTA in 2021. Additionally, a number of Persons Designated (PDs) from different groups have been added to the licence and others replaced to reflect business changes and priorities. There are currently 15 PDs on the licence (and seven have been removed). Four satellites were added to the licence between 2014 and 2019.

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

There are 47 standards under the Human Tissue Act 2004 ('HT Act'). Some standards are not applicable as establishment staff do not directly seek consent [standards C2(a)-(c)]. All other standards were assessed (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed, temperature monitoring records, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, minutes of meetings, the management of complaints, staff training records, and risk assessments.

Four of the establishment's internal audits and nine reported adverse events were reviewed.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

No formal audit of records was carried out by the HTA.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, CLHc, 14 PDs (including those based at the hub and all four satellites), the Global Head of Biobanks, the UK Biobank Lead, the Director of Human Tissue Compliance, the Biobank Technology Lead, a Senior Biobank Scientist, two Biobank Scientists and three Biobank Technicians. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 14 January 2022

Report returned from DI: 17 January 2022

Final report issued: 21 February 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 Inspection Report.

Date: 14 February 2023

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.