Inspection report on compliance with HTA licensing standards
Inspection date: **2 March 2023**

National Institute of Biological Standards and Control (NIBSC)

HTA licensing number 12321

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
National Institute of Biological Standards and Control	Licensed	Not licensed

Summary of inspection findings

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

Although the HTA found that National Institute of Biological Standards and Control ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and quality systems (records management).

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	The establishment did not have provisions in place to recover information held on paper records in the event of their loss.	**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.	C1(a)	The DI is advised to make provisions for the name, signature and date of the person who has obtained consent to be recorded on the consent forms. This will help to maintain an audit trail and provide assurances that consent seekers had completed up to date training at the time of obtaining consent.

2.	C1(a)	The project information sheet contains pertinent information in relation to risks and how donors can withdraw consent. To strengthen the consenting process, the DI is advised to consider including a box or other documented check step on the consent form for the donor to confirm receipt of the project information sheet rather than to rely on a pre-written statement that the donor has received it.
3.	GQ1(a)	The DI is advised to expand the checklist in SOP 5591- Record of collection, storage, use and disposal of human tissues to cover sample loss in transport, and link it to adverse event reporting procedures to ensure suitable actions are taken to resolve any identified issues.
4.	T1(c)	The DI is advised to review all of the processes that support end-to-end traceability to improve system integration, consistent data recording and to make information more accessible. Linked processes in scope for review should at least include: registers of donated material, consent documentation, transfer agreements and records of sample uses and disposal.
5.	T1(c)	The DI is advised to include a box or other documented check step on the Human Materials Advisory Committee (HuMAC) application form to confirm the person applying to work with relevant material has completed up to date consent and relevant material training. This will help to provide additional assurance that expected training requirements have been met.

Background

The principal activities of this establishment are the control and evaluation of biological medicines, and the development and provision of biological standards and other reference materials.

The National Institute of Biological Standards and Control has been licensed by the HTA since August 2007. This was the second inspection of the establishment; the most recent previous inspection took place in September 2012.

Since the previous inspection, there have been no significant changes to the activities carried out under the licence but the establishment has recently undergone large scale transformation with the new organisational model focused on improving the outcomes delivered to patients and the public.

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

46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard was not applicable as the establishment does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

Review of governance documentation

The inspection covered a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents, temperature trend records, risk assessments, minutes of meetings, a review of the traceability database, and audits.

Visual inspection

No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the storage facility and security arrangements.

Audit of records

The most recent quality management system audit and training review audit were reviewed as part of this inspection. Records held on the Tissue Tracking Database were also examined.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, the Person Designated working under the licence, and a number of project scientists. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 20 March 2023

Report returned from DI: 22 March 2023

Final report issued: 11 April 2023

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: 6 June 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.