

Licence application assessment report on compliance with HTA licensing standards
Site visit date: **29 January 2025**



Nexus BioQuest

Proposed HTA licensing number 12795

Application for a licence under the Human Tissue Act 2004

Activities

Premises/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
Nexus BioQuest (Bristol)	Applied made	Application not made

Summary of findings

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

The HTA found that Nexus BioQuest ('the establishment') had met all HTA standards.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C1(a)	Although the establishment will not be involved directly in managing donor withdrawal of consent, there may be occasions where suppliers may ask for samples to be removed from research activities. The prospective DI should consider documenting the process which should be followed should such a request need to be managed.
2.	C1(c)	The establishment will seek assurance that consent is in place before human tissue is purchased from suppliers by requesting consent templates and setting up suitable agreements. To strengthen the approach, the prospective DI should consider creating a checklist for each supplier to complete. This will help provide an evidential trail that a supplier has met the key requirements before tissue can be received.
3.	GQ1(a)	The establishment's procedure ' <i>NBQ-QMSSOP010, HTA Specimen</i> ', states that the sample database must be completed once disposal has taken place but does not describe the steps that should be taken to update it. The prospective DI should consider adding this information.
4.	GQ3(b)	Although new staff are expected to read standard operating procedures (SOPs) and the HTA's Codes of Practice, the prospective DI should consider introducing specific training on the regulatory and legal

		requirements relating to their human tissue work as part of induction training.
5.	GQ3(b)	The establishment has a staff competency sign-off system for laboratory processes. The prospective DI should consider adding a competency sign-off process to the existing system for staff working with human tissue. This would enable the competency of staff carrying out licensable activities to be formally recorded.
6.	T1(c)	The establishment has implemented changes to an existing sample database system, which is currently undergoing testing. The prospective DI should ensure that all testing of the database is clearly documented so that there is a clear audit trail to demonstrate that it is working as expected before tissue samples are recorded on the system.
7.	PFE2(d)	The establishment has a document called ' <i>Plan for fridge freezer failure</i> ', which is an uncontrolled document. As this document sets out the contingency plans in the event that a freezer failure occurs, the prospective DI is advised to include it in the quality management system.

Background

Nexus BioQuest is a contract research organisation which plans to purchase human tissue from suppliers including from outside of the UK. The establishment does not plan to seek consent directly.

Description of activities undertaken during the assessment

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the assessment:

Standards assessed

Of the 47 HTA licensing standards that could apply, 38 were assessed (standards published 3 April 2017). HTA standards, C1(b),(d),(e),(f) and C2(a),(b),(c) were not applicable as the establishment is not directly involved in seeking consent. HTA Standard PFE2(b) was not applicable as the establishment will not be storing the deceased.

Review of governance documentation

A review of policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audit procedures, risk assessments, incident reporting procedures, temperature monitoring for the storage units and staff training competency procedures was undertaken.

Visual inspection

A visual inspection of the laboratory where tissue would be received and stored was carried out. The laboratory contains two -80⁰c freezers and a -150⁰c freezer in a separate room. There was an appropriate access control system in place where human tissue would be stored.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI, Corporate Licence Holder contact (CLHc) and Persons Designated (PDs) involved in the licence application process.

Report sent to proposed DI for factual accuracy: 21 February 2025

Report returned from proposed DI: 24 February 2025

Final report issued: 3 March 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 site visit 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, and;
- 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, or;
- 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 site visit.

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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.