

Inspection report on compliance with HTA licensing standards
Inspection date: **5 June 2023**



Oxford BioDynamics Plc
HTA licensing number 12571

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
Oxford BioDynamics Plc	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.

Oxford BioDynamics Plc ('the establishment') was found to have met all HTA standards.

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

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 form template. This will help maintain an audit trail and provide assurance that the consent-seeker had completed up-to-date training at the time consent was obtained.
2.	C1(d)	To optimise assurances for informed consent, the DI is advised to provide a Patient Information Sheet to potential donors detailing project information and the risks associated with donation if this activity is to recommence. This information should describe the likelihood of adverse occurrences and their severity, in a format all potential participants are likely to understand. Information on how to withdraw consent - and who to contact - should also be provided.
3.	C2(c)	The DI is advised to extend the external Medical Research Council (MRC) human tissue training to Project Managers working with tissue and cells and in addition, the DI should consider regular refresher MRC training for all staff working with relevant material to support knowledge of regulatory and governance requirements.
4.	GQ1(a)	Relevant material donations are currently not collected from staff. If this activity were to recommence the DI is advised to have a clear and accurate standard operating procedure (SOP) in place covering consent procedures which comply with the Human Tissue Act 2004 and the HTA's Codes of Practice.
5.	GQ1(a)	SOP-002 HTA Compliance references serious adverse events and reactions (SAEARs), which are relevant to the

		HTA's Human Application and Organ Donation and Transplant sectors, and the requirement to report these to the HTA. The DI is advised to amend the wording within the SOP to reflect expectations for research sector establishments - if a DI has concerns about an adverse event, they are encouraged to contact us for further advice but there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA.
6.	GQ6(c)	All risk assessments are available to employees and the DI is advised to ensure new starters are made aware of risks during their induction training and where assessments can be accessed on the establishment's IT system.

Background

Oxford BioDynamics Plc was spun out from Oxford University in 2007. The establishment designs technical biomarkers and commercialised blood tests for clients.

Oxford BioDynamics Plc has been licensed by the HTA since 16 August 2010. This was the second inspection of the establishment; the most recent previous inspection took place in December 2014.

Since the previous inspection, the establishment has moved to larger premises within the same business park and a new DI has been appointed.

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 did not store bodies or body parts [standard PFE2(b)] under the research licence.

Review of governance documentation

The inspection comprised a review of documentation relevant to the establishment's licensed activities including; policies and procedural documents, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, a review of the tissue traceability database, staff training records, temperature monitoring for the storage units and audits.

Visual inspection

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

Audit of records

Samples relating to a project were reviewed on the tissue traceability database along with corresponding transport and consent documentation, material transfer agreement and disposal records.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: the Designated Individual (DI), the Person Designated (PD), two assistant PDs, and the named Corporate Licence Holder representative. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 19 June 2023

Report returned from DI: 22 June 2023

Final report issued: 23 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.