Inspection report on compliance with HTA licensing standards
Inspection date: **28 September 2021**

Intertek Clinical Research Services

HTA licensing number 12169

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 Intertek Clinical Research Services	Licensed*	Not licensed
Satellite site Intertek Pharmaceutical Services Manchester	Licensed*	Not licensed

* = Establishment is licensed to carry out this activity but is not currently carrying it out.

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.

Intertek Clinical Research Services ('the establishment') was found to have met all HTA standards. The establishment is not currently storing relevant material for a scheduled purpose.

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 ensure the following when activities under the licence resume:

Number	Standard	Advice
1.	GQ2(a)	When written consent for the storage of relevant material for use for a scheduled purpose (such as 'Research in connection with disorders, or the functioning, of the human body'), the DI is advised to regularly audit consent forms for completeness, accuracy, and legibility.
2.	T1(a)	The DI is advised to ensure that there is robust evidence of an identification system which assigns a unique code to each donation and to each of the products associated with it.
3.	T1 (c)	The DI is advised to ensure that evidence of a robust audit trail is maintained which includes where and when material was acquired and received, consent obtained, all sample storage locations, the uses to which any material was put and to whom.
4.	T2(b)	The DI is advised that the reason for disposal of human tissue is clearly recorded.

Background

Intertek Clinical Research Services provides clinical evaluation of personal care and healthcare products. The establishment provide studies for *in vitro* oral care product testing at the hub site and bioanalysis of clinical samples to support product development at the satellite site. Teeth are collected with consent from donors from a network of dental practices. Saliva is collected with consent from staff volunteers and stored before rendering acellular for use. All samples are from living donors and are anonymised. The establishment is not carrying out licensable activities but expects it may do so in the future and wishes to retain its licence.

The satellite site stores clinical samples with current ethical approval from a recognized Ethics Committee. These samples are for analysis in support of clinical trials. The samples are supplied by sponsor companies who have obtained ethical approval for the clinical trial and informed consent from the subjects. Samples are transported to the site for analysis in accordance with the tests specified in a clinical protocol and are not used for any other research purpose. At the end of the clinical study, the sponsor is contacted to determine the fate of the samples.

Intertek Clinical Research Services 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 November 2010.

Since the previous inspection, there has been a reorganisation of the establishment and reduction in activities.

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

Standard PFE2(b) was not applicable to the activities which may be undertaken by the establishment in the future. All remaining 45 licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspector undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to all licensed activities, consent documentation, standard operating procedures, and traceability systems. Documents detailing risk assessments and audits were also reviewed.

Visual inspection

There was no site visit inspection associated with the assessment.

Meetings with establishment staff

The inspection included discussions with the DI, the Laboratory Manager at the hub site, Head and Project Lead for Quality Assurance, Team Leader for Clinical Trials at the satellite site and the Facilities Compliance Manager.

Report sent to DI for factual accuracy: 19 October 2021

Report returned from DI: 15 November 2021

Final report issued: 16 November 2021

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.