

Licence application assessment report on compliance with HTA licensing standards

Site visit date: **no visit undertaken**



Inivata Limited

Proposed HTA licensing number 12707

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

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
Inivata Limited	Applied to be licensed	Not applied to be licensed

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.

Although the HTA found that Inivata Limited (the 'establishment') had met the majority of the HTA's licensing standards, one minor shortfall was found in relation to risk assessments. During the application assessment, the HTA found that the establishment was already storing relevant material that required a licence to be in place. This matter has been dealt with separately.

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(a)	<p>Documented risk assessments cover most of the practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. However, risks pertaining to consent are not adequately covered; for example, receiving and/or storing specimens without appropriate consent documentation and storing and/or using human tissue after consent withdrawal.</p> <p>Further guidance on risk assessments of activities conducted under the licence can be found in the HTA's research sector licensing standards and guidance document, which is available on the HTA's website.</p>	Minor

Advice

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

Number	Standard	Advice
1.	GQ3(a)	The proposed DI is advised to assure that all staff involved in undertaking licensed activities are aware of the requirements of the HT Act and the HTA's Codes of Practice. Specific training should be provided and refreshed as appropriate. It also may be valuable to include reference to the HTA's Code of Practice A (Consent) and E (Research) within appropriate training documentation.
2.	T1(c)	A sample submission form is completed for all samples received by the establishment, detailing information relating to the study and sample. The proposed DI is advised to include a check box within this spreadsheet to

		document that consent has been checked and assured by the sending establishment. This check should also be documented within the relevant SOPs.
3.	PFE2(d)	Contingency arrangements are documented; however, the current SOP does not detail the exact locations of the contingency fridges and freezers. The DI is advised to detail this to ensure that staff are aware of the full range of actions to be taken in the event of an alarm.

Background

Inivata provides Next-Generation Sequencing (NGS) testing relevant to Non-Small Cell Lung Cancer (NSCLC) to physicians, health care providers, and for clinical research. The establishment has applied for a HTA licence for the storage of relevant material, which has come from a human body, for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.

Description of activities undertaken

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

Standards assessed

42 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent were not applicable as the establishment does not seek consent from donors (C1(e), C1(f), C2(a), C2(b) and C2(c)).

Review of governance documentation

Policies and procedural documents relating to all licensable activities - including standard operating procedures, risk assessments and traceability systems - were assessed. Documents detailing the plans for staff training, adverse events, incidents, governance meetings and audits were also reviewed.

Visual inspection

There was no site visit.

Meetings with establishment staff

The assessment also included a virtual meeting with the proposed Designated Individual (DI), the proposed Corporate Licence Holder contact (CLHc) and the Senior Quality Assurance Manager.

Report sent to proposed DI for factual accuracy: 07 December 2020

Report returned from proposed DI: 17 December 2020

Final report issued: 18 December 2020

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.