Licence application assessment report on compliance with HTA licensing standards
Site visit date: **17 November 2023**

# Scancell Ltd

Proposed HTA licensing number 12768

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 |
|---|---|---|
| **Hub**<br>Scancell Ltd, Oxford Science Park | Applied to be licensed | Not applied to be licensed |
| **Satellite**<br>Scancell Ltd, University of Nottingham | 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 Scancell Ltd ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against the standard for Governance and quality systems which related to risk assessments.

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 application assessment.

**Compliance with HTA standards**

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| (a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice | Although the establishment has a suite of risk assessments relating to health and safety, risks relating to licensable activities have not been included.<br>Furthermore, the establishment has not risk assessed the storage spaces at the satellite site which are shared by other human tissue users working under a different HTA licence.<br>*Prior to the final report being published the DI submitted evidence of the actions taken in relation to this shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be now met.* | **Minor** |

**Advice**

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

| Number | Standard | Advice |
|---|---|---|
| 1. | GQ1(a) | There is reference to blood samples being obtained from laboratory staff in the 'Safe and appropriate use of Human Tissues' document. The proposed DI is advised to make it clear that this activity is carried out by collaborators who work under a project-specific research ethics committee (REC) approval and not directly at Scancell Ltd. |
| 2. | GQ1(a) | The transport SOP covers consent and receipt of samples, which may be misleading. The proposed DI is advised to consider renaming the SOP to make it clear what procedures are covered. Alternatively, the proposed DI may wish to separate out the procedures into a greater number of SOPs. |
| 3. | GQ1(a) | The Human Tissue Act 2004 is referenced in the establishment's policies and SOPs. The proposed DI is advised to consider referencing the HTA's Codes of Practice A (Consent) and E (Research), as well as the Standards and Guidance documentation, all of which provide practical information relating to compliance. |
| 4. | GQ2(a) | Staff at the establishment discussed a range of audits that will be carried out covering all licensable activities. Not all scheduled audits have been detailed within the audit SOP. The proposed DI is advised to include the planned external audit and annual audit covering HTA standards within the document.<br>The proposed DI is also advised to add specific dates within the schedule to ensure that they are carried out in accordance with the intended timelines. |
| 5. | GQ5(a) | The establishment has a detailed SOP outlining the process for incident reporting. To improve staff awareness, the proposed DI is advised to provide more examples of what types of incidents are to be reported that relate to licensed activities, such as specimen loss, incorrect documentation, use of relevant material without appropriate consent and loss of traceability (this is not an exhaustive list). |

| | | |
|---|---|---|
| 6. | N/A | To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the proposed DI is advised to consider improving signs on the fridges, freezers and cabinet, highlighting that human samples are contained within. |

**Background**

Scancell Ltd is a clinical stage biopharmaceutical company. 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 during assessment**

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

*Standards assessed*

40 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 intend to directly seek consent from donors (C1(b), C1(d), 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 overarching policies and standard operating procedures were assessed. Documents detailing the plans for staff training, incident management, governance meetings and audits were reviewed. The establishments sample traceability systems were also assessed.

*Visual inspection*

The Regulation Manager undertook a visual inspection of the premises at the hub site which included the laboratory spaces. The security arrangements and the suitability of the storage areas were assessed. The plans for temperature monitoring, alarming, maintenance, contingency and cleaning of the storage units were reviewed.

*Meetings with establishment staff*

The Regulation Manager met with staff carrying out activities under the licence, including scientists, the Quality Team, the Laboratory Manager and the Head of Translational Research who is the proposed DI.

**Report sent to proposed DI for factual accuracy:** 23 November 2023

**Report returned from proposed DI:** No factual accuracy or request for redaction comments were made by the proposed DI

**Final report issued:** 23 November 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 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.