Licence application assessment report on compliance with HTA licensing standards
Site visit date: **28 November 2023**

T-Therapeutics Limited

Proposed HTA licensing number 12767

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
T- Therapeutics Limited **Riverside 3, Suite 1** (Granta Park, Cambridge)	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 T-Therapeutics (the establishment) had met the majority of the HTA's standards, one minor shortfall was found against Governance, quality and systems standards, in relation to records relating to tissue disposal.

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 visit.

Compliance with HTA standards

Minor Shortfalls

GQ4 There is a systematic and planned approach to the management of records		
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.	The establishment plans to document tissue disposal within the laboratory records used to record processes and studies that use human tissue. This information would be stored separately to traceability records for each sample and may be subject to different back-up arrangements.	**Minor**

Advice

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

Number	**Standard**	**Advice**
1.	C1(a)	The establishment may receive material obtained from the deceased donors in the future. The DI is advised to ensure they understand the consent requirements for storing and using tissue removed from deceased donors for scheduled purposes under the Human Tissue Act 2004 and make sure these are reflected as appropriate in relevant documents.

2.	C1(a)	The prospective DI is advised to consider developing a new supplier proforma that evidences consent for research is in place before tissue is purchased for storage and use for research. This will help to provide an audit trail for assurance that necessary checks were undertaken.
3.	GQ1(a)	The prospective establishment has procured a bespoke traceability system that has been user-tested and for which training will be rolled-out to all staff who will be using it. Although current procedures outline the fields that should be completed by users, the prospective DI should consider developing work instruction/s or including more detailed information on how the system should be populated in a step-wise fashion. This will help to reduce the risk that information is recorded inconsistently.
4.	GQ1(b)	Document control is being managed using a manual process. The prospective DI may wish to consider using a quality management software to help oversee the review cycles of procedures, potentially reducing the risk that reviews may be missed through human error.
5.	GQ2(b)	HTA-SOP-005 sets out the audit process. The prospective DI should consider documenting the expectations for how the audit proforma should be completed to ensure that enough detail is recorded during audits. This should help to maintain audit quality and consistency.
6.	GQ3(a)	The establishment has a process for documenting training competencies of staff working with human tissue. The probation form, which is for new starters working with human tissue, could also include the date by which a key training milestone was reached. This may help to formally document and monitor individual training, supporting the identification of training needs.
7.	GQ6(a)	Document RX121 documents the risks associated with HTA licensable activities. To assist with ongoing risk management, the proposed DI is advised to consider the adoption of a conventional risk matrix approach.

Background

The establishment is a private company whose work focusses on genomics and drug discovery and development to treat oncological and inflammatory diseases. It plans to procure tumour, inflamed tissues and normal cells and tissues including peripheral blood mononuclear cells (PBMCs) from living patients. There are also plans to work with the same range of tumours, cells and tissues from deceased donors in the future.

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, 46 were assessed (standards published 3 April 2017). PFE3(c) was not applicable due to the material to be stored under a licence.

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, meeting minutes, temperature monitoring for the storage units and staff training records.

Visual inspection

A visual inspection was carried out of the laboratory where tissue would be received and the storage areas which accommodate a -80°C freezer and a -150°C freezer.

Meetings with establishment staff

A roundtable meeting was held with the prospective DI and PD as well as other members of staff who would be working with human tissue.

Report sent to proposed DI for factual accuracy: 18 December 2023

Report returned from proposed DI: 9 January 2024 (with comments)

Final report issued: 9 January 2024

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 11 April 2024

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.