Licence application assessment report on compliance with HTA licensing standards
Site visit date: **4 November 2022**

T-Cypher Biotherapeutics Ltd

Proposed HTA licensing number 12744

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-Cypher Biotherapeutics Ltd	Applied to be licensed	Not applied to be licensed

Summary of visit 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-Cypher Biotherapeutics Ltd (the 'establishment') had met the majority of the HTA's standards, one minor shortfall was found against a Consent standard, relating to the content of the establishment's donor consent form and associated information sheet.

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 shortfall identified during the visit.

Compliance with HTA standards

Minor Shortfalls

Standard	Visit findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	To prevent any unlawful storage of relevant material prior to a licence being authorised, the establishment's internal template consent form did not allow consent for storage of samples from staff to be recorded. In addition, the associated Healthy Donor Information sheet stated that none of the donor's sample will be stored. No suitable updated documents, for use after a licence is granted, were available for review. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(c)	The proposed DI is advised to implement a documented process for the current practice of seeking an assurance that appropriate consent is in place from other parties providing relevant material, to ensure

		that consent is obtained in accordance with the requirements of the HT Act.
2.	C2(a)	The proposed DI is advised to consider supplementing the current consent training, provided by an external organisation, with additional training that specifically addresses the requirements of the HT Act and the HTA's Codes of Practice. Official HTA guidance is published on our website and should be considered as the definitive source of information for matters within our remit.
3.	T1(b)	In addition to its plans to store relevant material under an HTA licence, the establishment also stores material that is exempted from HTA licensing requirements, from Research Tissue Banks and under other approvals from recognised Research Ethics Committees (RECs). To improve awareness and oversight of storage for all material, the proposed DI is advised to record and track the expiry dates of REC approvals, and any other limitations on the use and / or storage of the material.

Background

T-Cypher Biotherapeutics Ltd is a privately-held company that has applied for an HTA licence to store relevant material which has come from a human body for use for scheduled purposes. The establishment intends to conduct research utilising a proprietary platform and will receive relevant material from commercial suppliers, research tissue banks, collaborators, or collected from volunteer donors.

Description of activities undertaken during visit

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

Standards assessed against during visit

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not intend to store material from the deceased (standards published 3 April 2017).

Review of governance documentation
The visit included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, equipment records, risk assessments, arrangements for temperature monitoring for the storage units, and a review of the database that will be used to record and track relevant material.

Visual inspection
The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment, the phlebotomy area, and areas where samples will be stored.

Meetings with establishment staff
The visit included meetings and discussions with the proposed Designated Individual (DI), the proposed Corporate Licence Holder contact and other staff who will be working under the licence including the Lab Manager, the Health and Safety officer, a Senior Scientist, and a Staff Scientist.

Report sent to proposed DI for factual accuracy: 2 December 2022

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

Final report issued: 23 December 2022

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.