Licence application assessment report on compliance with HTA licensing standards
Site visit date: **24 October 2023**

Enhanc3D Genomics Ltd

Proposed HTA licensing number 12764

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
Enhanc3D Genomics 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 Enhanc3D Genomics Ltd (the establishment) had met the majority of the HTA's standards, 4 minor shortfalls were found against standards for Governance and quality systems.

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 assessment.

Compliance with HTA standards

Minor Shortfalls

Standard	Visit findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment did not have a standard operating procedure (SOP) for the undertaking of audits and follow-up corrective and preventative actions. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
c) There are change control mechanisms for the implementation of new operational procedures.	The establishment did not have change control mechanisms for the implementation of new operational procedures taking into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The establishment did not have a documented schedule of audits covering licensable activities. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

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.	The establishment did not have documented risk assessments for all practices and processes connected with licensed activities including risks related to: • receiving and/or storing specimens without appropriate consent documentation • storing or using human tissue after consent withdrawal • storage failure or other damage affecting human tissue quality for useful research • loss of human tissue • sample mix-up or loss of traceability • transport of specimens to and from the establishment • security arrangements • incorrect disposal. *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.	GQ1(a)	The proposed DI is advised to amend SOP-Lab General_EG001_Storing Relevant Material to ensure the disaster recovery protocol includes the process step of recording the new relevant material storage location(s) in the tissue tracking database to ensure traceability is maintained in the event of critical storage failure.
2.	GQ1(a)	The proposed DI is advised to amend SOP_ Lab General_EG006_General Sample Management in the following areas to provide an accurate representation of processes and practices and to ensure traceability: • to include a process step confirming any non-conformity discovered on receipt of relevant material at the establishment is reported as an adverse event • to confirm the DI is to sign off adverse event corrective and preventative actions • to set out and include timeframes for the completion of corrective and preventative actions for adverse events • to identify and record where completed relevant material sample disposal forms are to be stored.
3.	GQ1(d)	Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. The proposed DI is advised to develop the standing agenda to include relevant headings to ensure all matters relating to the licence are identified and discussed during governance meetings.
4.	GQ3(a)	A spreadsheet of completed staff training is maintained. The proposed DI is advised to include an additional column within the spreadsheet to identify the date staff refresher training is due to improve the ease in which employees can be identified and ensure training is arranged and completed in line with the establishment's

		policies and procedures.

Background

Enhanc3D Genomics Ltd are a functional genomics company exploring the 3D organisation of DNA in health and disease and the development of biomarkers.

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

43 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Four standards were not applicable as the establishment does not have staff involved in seeking consent [standards C2(a), (b) and (c)] and does not intend to store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, adverse event reporting, training requirements, temperature monitoring of the relevant material storage areas, equipment servicing records, contingency plans and a review of the HTA tissue tracking 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 and stored.

Meetings with establishment staff

The assessment included meetings and discussions with the proposed DI, Person Designated, Lead Scientist, Office Manager and Chief Operations Officer.

Report sent to proposed DI for factual accuracy: 1 November 2023

Report returned from proposed DI: 13 November 2023

Final report issued: 11 December 2023

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: 1 December 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.