Licence application assessment report on compliance with HTA licensing standards
Site visit date: **21 May 2024**

Illumina Cambridge Limited

Proposed HTA licensing number 12774

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
Illumina Cambridge 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.

The HTA found that Illumina Cambridge Limited (the establishment) had met all HTA standards.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	GQ5(a)	The proposed establishment has in place a standard operating procedure (SOP) that deals with incidents and near-misses. All staff are expected to report incidents that involve non-conformances that arise during handling of human tissue. The proposed DI should consider providing examples of incidents involving human tissue, in the documented procedure, that would need to be reported and investigated.
2.	GQ6(a)	The risk assessments are wide in scope and include activities that will be carried out under HTA licence. Although the proposed establishment is not involved in seeking consent and has a process to ensure that only samples with appropriate consent are stored, the proposed DI should consider extending the scope of the existing risk assessment to include receiving specimens without appropriate consent.
3.	T2(b)	There may be occasions where the proposed establishment is required to dispose of samples, following client instruction. For example, if a donor withdraws their consent. In these circumstances, the sample management team will inform the laboratory team to dispose of the samples. To strengthen the process further, the proposed DI should consider defining a timeframe in which samples must be disposed of, to help ensure that disposal is carried out promptly.

Background

The establishment provides sequencing and micro array technologies on behalf of clients. The establishment extracts DNA from blood which has clinical uses, including molecular diagnostics. The establishment intends to store blood for research purposes under the Human Tissue Act 2004.

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, 39 were assessed (standards published 3 April 2017). HTA standards, C1(b),(d),(e),(f) and C2(a),(b),(c) were not applicable as the establishment is not directly involved in seeking consent. HTA Standard PFE2(b) was not applicable as the establishment will not be storing the deceased.

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 procedures, temperature monitoring for the storage units and staff training competency procedures was undertaken.

Visual inspection

A visual inspection was carried out of the laboratory where tissue would be received and stored. The laboratory contains a fridge and freezer where samples will be stored. There is also a contingency fridge and freezer to enable material to be re-located in the event of a storage failure.

Meetings with establishment staff

A roundtable meeting was held with the proposed DI and key staff involved in the licence application process, including the Quality Assurance Managers, Project Laboratory Manager and Senior Clinical Laboratory Manager.

Report sent to proposed DI for factual accuracy: 7 June 2024

Report returned from proposed DI: 21 June 2024

Final report issued: 24 June 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.