Licence application assessment report on compliance with HTA licensing standards
Assessment date: **12 May 2022**

ACM Global Laboratories

Proposed HTA licensing number 12735

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
Building 23 Hospital Fields Road (Hub) **(Hub)**	Applied to be licensed	N/A
Building 36 Hospital Fields Road **(Satellite)**	Applied to be licensed	N/A

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.

ACM Global Laboratories ('the establishment') was found to have met most of the HTA standards; however, two minor shortfall were identified against standards for Consent (staff training) and Traceability (documentation of disposal).

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

Standard	Assessment Findings	Shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addressed the requirements of the HT Act and the HTA's Codes of Practice.	There was no evidence that HTA consent training would be provided to phlebotomy staff who will be involved in seeking consent from healthy volunteers.	**Minor**

Standard	Assessment Findings	Shortfall
T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and method used are documented.	The SOP about managing control matrices does not include that the date, reason and method of disposal should be documented.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	There is a clause included in the consent form for consent withdrawal; however, the SOP that covers consent, does not provide any steps on how this should be documented or by whom. The prospective DI should include steps on the procedure for documenting consent withdrawal in the relevant SOPso it is clear to staff.
2.	C1(d)	The HT Act requires that consent is obtained for the storage of human tissue within its scope. As storage is not referenced on the consent form, the prospective DI is advised to review consent procedures and supporting documentation to assure himself that consent for storage can be suitably evidenced.
3.	C1(d)	The information sheet informs the participant that relevant material would be kept for a period of two years but does not state what would happen to it after this period. The DI should consider reviewing and revising this written information to include disposal arrangements.
4.	GQ1(a)	The SOP about internal audit is comprehensive and covers different audit approaches. Section 6 of this SOP references several regulatory bodies that have remits relevant to activities taking place on the premises. In consideration of the granting of a HTA licence, the prospective DI may also wish to consider adding HTA to this section.
5.	GQ2(a)	The prospective DI plans to review the approach to audits in consideration of HTA-licensed activities, including the traceability of human tissue. The prospective DI may wish to consider auditing with reference to HTA standards.

6.	GQ5(a)	The prospective DI is advised to consider adding a section to the SOP that covers adverse events to support staff in recognising adverse events relevant to activities regulated by the HTA. Relevant examples of adverse events include: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • inappropriate disposal
7.	GQ6(a)	The establishment has undertaken a thorough assessment of risks against the overarching HTA standards. To strengthen this further, the prospective DI should consider reviewing the risk assessments to ensure that security considerations are clearly documented.
8.	T1(c)	The establishment intends to use paper-based systems to support traceability, as the number of samples to be stored at any one time will be limited. The prospective DI may wish to consider whether an electronic system would more effective should activity increase or if the paper-based system of managing traceability subsequently becomes less suitable for its intended purpose.

Background

ACM Global Laboratories (the ‘establishment’) is a laboratory that specialises in clinical trials work and will be storing human tissue for validation purposes which is purchased from a HTA-licensed establishment. There will be a satellite site, which will operate under the same governance as the hub site and carry out the same activities. The establishment intends to store a small amount of human tissue on the premises, which would either be purchased from approved vendors or collected from healthy volunteers (staff).

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 assessment:

Standards assessed against during visit

44 of the 47 HTA licensing standards were covered during the visit (standards published 3 April 2017). Standard PFE2(b) is not applicable as only tissue from living donors will be stored. As the establishment plans only to store tissue and not transport it elsewhere, standards T1(f) and (g) are not applicable.

Review of governance documentation

Key SOPs and policies were reviewed as part of the licence application assessment, which included - but was not limited to - the following areas:

- Managing Corrective and Preventative Actions
- Regulatory Requirements
- Records Retention and Management
- Sample Collection
- Audit process
- Traceability
- Adverse Events

Visual inspection

A virtual tour of the hub site facilities was provided at the time of the licence application assessment. This included the laboratory and the freezer storage room, where human tissue will be stored.

Meetings with establishment staff

A roundtable discussion was carried out with the proposed DI and proposed CLHc.

Report sent to proposed DI for factual accuracy: 9 June 2022

Report returned from proposed DI: 17 June 2022 (with comments)

Final report issued: 27 June 2022

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: 5 Ocotober 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.