Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **09 January 2020**

Mogrify Ltd

Proposed HTA licensing number 12698

Application for a licence under the Human Tissue Act 2004

Activities 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
Mogrify Ltd	To be licensed	Not 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.

Mogrify Ltd (the 'establishment') was found to have met all HTA standards.

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

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.	C1(c)	Relevant standard operating procedures (SOPs) and risk assessments - such as the SOP for receiving human tissue and cells, and the risk assessment related to receiving and / or storing human tissue without consent - stipulate that relevant material will only be received into the establishment if consent documentation is available. However, the documents also indicate that it is the responsibility of the commercial supplier, or collaborator, to ensure that appropriate consent is in place. The proposed DI is advised to amend the documentation to clarify that, as the proposed DI has oversight of all relevant material stored under the licence, they must be assured that all material has been sourced consistently with the Human Tissue Act 2004 (HT Act) and the HTA's Codes of Practice.
2.	GQ1(a)	The establishment has a procedure for responding to alarms out of normal working hours. To ensure that all staff are aware of the correct procedure, the proposed DI is advised to include it in the temperature monitoring and alarm SOP.
3.	GQ3(b)	The fridge and freezers that may be used for storing relevant material are contained within access-controlled laboratories, where all staff members have been trained in the requirements of the HT Act. As the company continues to expand, they may employ staff who will not work with relevant material. In order to provide an assurance that only staff trained in the requirements of the HT Act are able to access relevant material, the proposed DI is advised to consider a process where all staff are trained in the requirements of the HT Act as part of their induction or there is additional access control to the units where relevant material may be stored.
4.	T1(c)	The establishment intends to store relevant material in a rack in a locked -150°C chest freezer in a shared, controlled-access, basement room. The freezer has signage indicating that one of the racks contains human

		tissue, but this is not readily visible to other users of the room. The proposed DI is advised to make the signage clearer and more apparent.
5.	PFE2(c)	The establishment has purchased a commercially available continuous monitoring and alarm system for their fridge and freezer units. The proposed DI is advised to consider implementing a process to trend the routine temperatures of the units. Deviations in these temperatures may provide an early warning of a potential unit failure.

Background

Mogrify Ltd (the 'establishment') is a privately held biotechnology company that has applied for a HTA licence to store relevant material which has come from a human body for use for scheduled purposes. The company intends to conduct research aimed at modifying and improving cellular therapies. The establishment will only receive relevant material that has been purchased from commercial suppliers, or provided by collaborators.

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 38 were assessed. Standards C1a, C1b, C1d, C1e, C1f, C2a, C2b, C2c and T1g were not applicable (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, temperature monitoring for the storage units, staff training records, 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 and stored.

Meetings with establishment staff
The visit included discussions with the proposed DI and establishment staff involved with ordering and receiving relevant material, as well as those involved with governance and quality systems. As the proposed Corporate Licence Holder contact was not available on the day of the visit, advance discussions were held by telephone.

Report sent to proposed DI for factual accuracy: 31 January 2020

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

Final report issued: 13 February 2020

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
- 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
   - 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
- 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.