Licence Application Assessment Visit report on compliance with HTA licensing standards

Research Donors Limited

Proposed HTA licensing number 12693

Application to be licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

23 August 2019

Summary of inspection findings

The HTA found the proposed Designated Individual (DI), the proposed Licence Holder (LH), the premises and the practices to be suitable in accordance with the requirements of the legislation.

Research Donors Limited was found to have met all HTA standards.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the proposed Designated Individual 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 Designated Individual 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.

Background to the establishment

Research Donors Limited (the 'establishment') is a privately owned company that has applied for a HTA licence to store relevant material which has come from a human body for use for scheduled purposes. Research Donors Limited recruits healthy donors to provide samples for ethically approved biomedical research studies, both in the UK and abroad. Samples are collected in order to allow researchers to research the causes of disease and to develop new diagnostic tests and medicines. The establishment maintains a donor list and, currently, recruits donors in response to specific client requests.

Clients contact Research Donors Limited requesting a specific set of samples meeting pre-defined criteria. Staff review the current donor database and contact potential volunteers to provide samples. While volunteers may provide samples for a number of different clients, the establishment ensures that the total of all collections for each donor are within pre-defined limits, corresponding to recommended national blood donation guidelines. Donors are reconsented at every donation visit, and are screened for a panel of communicable diseases. Samples from different donors are 'batched' until a client order has been completed and then shipped to a client. As an unlicensed establishment, samples are not, currently, held on site for longer than seven days prior to shipment.

While the focus of the establishment is collection of whole blood, peripheral blood mononuclear cells, serum, and plasma, the establishment has also previously collected sputum and vaginal swabs.

The facility is contained within a secure building, requiring visitors to be granted entry via an intercom unit. Visitors, and donors, enter a reception area adjacent to the collection suite. Donors are assigned a unique ID at each collection visit and this ID is modified for each sample type and is retained by the samples throughout the process. The processing laboratory is entered through a secured door, and is restricted to laboratory personnel.

The laboratory currently contains two refrigerator units (4°C), one -20°C freezer and one -80°C ultra-low temperature freezer. All units are subject to an external maintenance schedule and alarm systems are validated and calibrated annually.

To facilitate the provision of panels of samples to clients, the establishment proposes to prospectively collect, and store, frozen samples in advance of client requests. In addition to the current refrigerator and freezer units, the establishment is considering expanding this capability to allow storage in vapour phase liquid nitrogen tanks.

Description of inspection activities undertaken

This report describes a licence application assessment site visit to assess the suitability of the establishment to hold a HTA licence. The suitability of the proposed DI and the proposed Corporate Licence Holder contact (CLHc) were also assessed. The proposed DI is the Managing Director for the establishment and the proposed CLHc is the company Director and sole owner. The inspection included a review of the establishment's procedures for conducting activities under the licence, a visual inspection of the areas where samples will be stored under the licence, and an interview with the proposed DI.

At the time of inspection, the establishment was not storing any relevant material that would require a HTA licence to be in place. However, the processes for recruiting and consenting donors, collecting and labelling samples, and tracking samples from collection to shipping were all in place and were reviewed during the visit. No issues were identified although advice has been provided (see *Advice*, items 1 and 2).

Inspection findings

The HTA found the proposed Licence Holder, the proposed Designated Individual and the premises to be suitable in accordance with the requirements of the legislation.

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:

No.	Standard	Advice
1.	C1(a)	In seeking to ensure consent is optimally informed and documented for traceability, the proposed DI is advised to further develop the consent documentation, including the consent form, to clarify more strongly that: - donor samples may be used for DNA extraction and analysis - donor samples may be used for animal research, including xenografts - donated material will be provided to clients commercially - donated material will be provided to clients and used in accordance with the consent which has been obtained - donated material may be exported to clients located outside of England, Wales and Northern Ireland in accordance with the requirements of the Human Tissue Act 2004 and HTA Code of Practice and Standards: E Research
2.	GQ1(a)	The Standard Operating Procedure that details the withdrawal of consent process stipulates that when a client withdraws consent any samples remaining at Research Donors Limited will be disposed of. The proposed DI is advised to consider options for the disposal of material that has been provided to clients, but not used at the time of withdrawal of consent.

Concluding comments

This report describes the licence application assessment of the suitability of Research Donors Limited to be licensed under the HT Act for storage of relevant material which has come from a human body for use for scheduled purposes.

The establishment is a commercial organisation that has previously been accredited by a number of external bodies. They have established, and maintained, a good system for tracking products which can be applied to maintain traceability and quality of relevant material stored under the HTA licence.

The HTA found the proposed DI, proposed Licence Holder, premises and the practices to be suitable for the activities specified.

Report sent to DI for factual accuracy: 20 September 2019

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

Final report issued: 09 October 2019

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code 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. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
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 addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
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. b) There is a document control system.

c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
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. b) Risk assessments are reviewed regularly. c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem.

c) Staff are provided with suitable personal protective equipment.

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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or 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 both the draft and final inspection report. You 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 desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.