Site visit inspection report on compliance with HTA licensing standards
Inspection date: **11 December 2019**

Royal Free Hospital
HTA licensing number 12406

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

and

Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment

Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Royal Free Hospital	E*		E	E	E		

Tissue types authorised for licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

'Authorised' = Establishment is authorised to carry out this activity and is currently carrying it out.

'Authorised*' = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export

Cardiovascular, Vessels; Other Vessels	Authorised*		Authorised	Authorised	Authorised		

Licensed activities – Human Tissue Act 2004

'Licensed' = Establishment is licensed to carry out this activity and is currently carrying it out.

'Licensed*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Royal Free Hospital	Licensed*

Summary of inspection findings

Although the HTA found that Royal Free Hospital (the establishment) had met many of the HTA's standards, three major and eight minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment. The major shortfalls related to the process of vessel release, the scope and undertaking of internal audits, the maintenance of establishment records, and reflected the insufficient embedding of procedures relating to these activities in response to findings identified in the last HTA site visit inspection. The minor shortfalls related to the content of establishment procedures, agreements with third parties, documentation of staff training, procedures for raw data and traceability data retention, procedures for the implementation of the Single European Code (SEC), the scope and review of establishment risk assessments, temperature monitoring and servicing of storage equipment, and equipment cleaning procedures.

The recurrent nature of a number of the shortfalls identified as part of the most recent site visit inspection is of concern to the HTA. The HTA considers that the DI has not taken adequate steps to address issues that were identified at the last inspection and embed suitable practices at the establishment.

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 inspection. However, the HTA will be maintaining oversight of the actions taken to address these shortfalls, and as part of this process will make a final assessment of the suitability of the DI.

In addition to this, since the last inspection, the establishment has procured fascia rectus in response to urgent patient need, without prior notification to the HTA. The HTA considers this a breach of the standard condition of the establishment's licence, which requires it to seek approval from the HTA prior to it procuring a new type of tissue and/or cells. The HTA will consider the need for regulatory action in relation to this matter separately to the inspection findings reported below.

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.	Establishment procedures set out that vessels are stored in the quarantine area of the tissue storage fridge until they are released for use by suitably trained staff. As part of the release procedure repeat serology tests are undertaken in accordance with Directions 002/2018. Results are reviewed and compared to the results obtained under the Organ Donation and Transplant (ODT) framework before the vessels can be moved to the 'verified' section of the fridge. This review is the responsibility of the establishment's Persons Designated (PDs). A number of issues were identified with the release process:	**Major**

	• establishment records and procedures do not prompt the reviewer to document that the release check has been undertaken, except where an issue is identified during the release process; • during the inspection, there were several vessels in the 'verified' section of the fridge available for use and distribution. Establishment PDs were not able to identify who had undertaken the release checks for these vessels. One PD responsible for checking samples within the tissue bank fridge was unfamiliar with the release process; • theatre PDs relied upon the establishment's electronic database to check second level serology results, but this database contained multiple errors and had not been updated in the two months prior to the inspection. Refer also to the shortfall under standards GQ4a and b; • theatre PDs are responsible for selecting vessels for use at the establishment and distribution to other establishments for end-use. Authorisation for the use of the chosen vessel by the PD where vessels are removed and packaged by another member of theatre staff is not captured in establishment records; and, • establishment procedures provide instructions on what to do if vessels must be released for end-use without the secondary serology results being available. The procedures further describe how this is communicated to the relevant clinical team to inform decision making, and how results are subsequently communicated when they become available. During the inspection, an example was seen in which a vessel transfer form had been completed with the primary serology information in the section intended for completion of the secondary serology results. This deviation was not evident within the form to inform the end-user, and staff were not able to set out the process they would follow to ensure this was flagged internally to ensure subsequent follow-up.	

	The presence and suitability of establishment procedures related to the release and distribution of vessels was a finding at the last inspection. The observations set out above indicate that the corrective actions implemented in response to the last inspection have not been effectively incorporated within the establishment's practices and governance systems.	
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Establishment audits had not been performed in accordance with the predefined schedule and examples were seen where audits were more than one year overdue. An audit of databases described in establishment procedures had not been undertaken. In addition, establishment audits did not include audits of temperature monitoring records or training records. The lack of internal audits of establishment databases, blood vessel transfer forms, and forms used to capture the batch numbers of storage pots and fluids was a shortfall at the last inspection. The overdue audits noted at this inspection, together with the findings listed under standards GQ1i, GQ4a, and PFE3a indicate that actions taken to resolve these issues following the last inspection have not been effectively embedded within the establishment's governance and quality systems.	**Major**

GQ4 There is a systematic and planned approach to the management of records.		
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.	The establishment has a number of electronic databases that are used to back-up information from the vessel logbook, cross-check the primary and second level virology results, and review the quarterly microbiology tests carried out on perfusion fluid samples from a subset of vessels for disposal. The maintenance and use of these databases are not adequately controlled or aligned with the establishment's procedures. Multiple copies of the databases were present in the shared computer drive, and different teams were working from different versions. The database used to capture serology results contained multiple gaps and errors. This had been identified in the establishment's independent audit and not addressed prior to the inspection. In addition, the database had not been updated in the two months prior to the inspection. No steps had been taken to address this issue or provide alternative means for theatre staff to determine if vessels were suitable for use and distribution. These findings were also identified at the last inspection. The database audit that had been introduced to help address the previous shortfall had not been carried out in accordance with the establishment's schedule.	**Major**
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.		

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	During the inspection, examples were identified where the establishment's standard operating procedures (SOPs) did not accurately reflect current practices: • the SOP describing the procedure for distribution of vessels to other establishments indicates that dry rather than wet ice is required to achieve the required transportation conditions. This is not aligned with the establishment's defined storage temperature for such vessels; and, • the SOP that describes vessel disposal procedures does not instruct the reader to include the disposal information in the traceability database.	**Minor**
q) There is a record of agreements established with third parties.	The establishment has not been able to provide a copy of their agreement with the organisation undertaking serology and microbiological testing related to vessels stored under the licence.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The establishment undertakes training against documented procedures, but there was no applicable training record for staff undertaking the logging in and removal of vessels from the tissue bank fridge. Records did not allow reviewers to determine whether all staff requiring training in a given activity had received it. One nurse undertaking licensable activities was not listed as having received the	**Minor**

	relevant training within the establishment's training records.	
GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	The establishment's quality manual states that equipment maintenance and service records are retained for the lifetime of the equipment plus two years. This is not aligned with the regulatory requirement to retain raw data for 10 years after the use, expiry date or disposal of tissues and/or cells. The establishment was not able to provide temperature records prior to 2011, and the records kept were incomplete. In addition, the establishment's policy for records management and retention had not been reviewed within the required period and does not specify the regulatory requirements for the retention of raw data. Whilst the policy states that records of traceability must be retained for 30 years, it does not explicitly require the establishment to retain these records for 30 years from the use, expiry date or disposal of tissues and/or cells.	**Minor**
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.		
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment's system for the implementation of the SEC does not comply with the regulatory requirement set out in Directions 002/2018, and is not supported by a documented procedure setting out how SEC codes are created, allocated, communicated and documented when vessels are distributed to other establishments for end-use.	**Minor**
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	The establishment has not sufficiently risk assessed the theatre premises with regards to the storage of vessels prior to use or disposal.	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	During the inspection a number of issues were identified related to the storage environment for vessels and reagents: • the fridge used to store vessels (the tissue bank fridge) and the back-up National Organ Retrieval Service (NORS) fridge used as a contingency were fitted with integrated continuous temperature monitoring devices, but on both fridges, these devices were broken. Independent temperature probes that had been fitted as an alternative monitoring solution did not provide continuous temperature monitoring; • Gaps were noted in the weekday manual monitoring records, and checks were not routinely undertaken at weekends; • the tissue bank fridge service had not been undertaken within the specified service period; and • establishment procedures had not been updated to reflect the current temperature monitoring procedures, following the failure of the integrated devices. Taken together, these findings do not provide sufficient assurance that reagents and tissues are stored in appropriately monitored environments and that excursions from the required temperature ranges will be identified and assessed by trained establishment personnel.	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	The establishment's procedures do not define the frequency at which fridges must be cleaned. During the inspection establishment staff reported that the vessel storage fridge was cleaned on a monthly basis. The establishment's 'vessel fridge	**Minor**

	housekeeping' record indicated that the fridge was cleaned in February 2019 and, prior to that, December 2016.	

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

DI and CLH suitability

The recurrent nature of a number of the shortfalls identified as part of the most recent site visit inspection is of concern to the HTA. The HTA considers that the DI has not taken adequate steps to address issues that were identified at the last inspection and embed suitable practices at the establishment.

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 inspection. However, the HTA will be maintaining oversight of the actions taken to address these shortfalls, and as part of this process will make a final assessment of the suitability of the DI.

In addition to this, since the last inspection, the establishment has procured fascia rectus in response to urgent patient need, without prior notification to the HTA. The HTA considers this a breach of the standard condition of the establishment's licence, which requires it to seek approval from the HTA prior to it procuring a new type of tissue and/or cells. The HTA will consider the need for regulatory action in relation to this matter separately to the inspection findings reported below.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1b	The establishment's quality manual and SOPs contain multiple references to the Human Tissue Act (HT Act) rather than the Human Tissue (Quality and Safety for Human Application) Regulations (the Q&S Regulations) under which the establishment is licensed to carry out its activities. The DI is advised to review and update these documents to ensure that establishment staff are provided with accurate information about the regulatory context under which licensable activities are taking place.
2.	GQ1i	During the inspection, it was noted that the secondary serology results were captured in the records for the recipient of the organ that the vessels are associated with, which can make searching for this information difficult for establishment staff. The DI is advised to ensure that all relevant staff are familiar with where to find these results, and investigate whether this system can be simplified to ensure serology results are readily available to staff for review.
3.	GQ3e	The DI is advised to implement systems to evidence that staff have read and understood the instructions set out in the current versions of establishment SOPs as they are published.
4.	GQ7h	The establishment has agreements with end-users which set out routes for SAEARs reporting to the HTA. In one example, the agreement set out that SAEARs reporting to the HTA at the recipient establishment would be managed under the end-user's HTA licence. The agreement did not set out systems for reporting SAEARs that could be linked to the quality and safety of the distributed vessel(s) back to the Royal Free for awareness and assessment. The DI is advised to update this agreement to ensure that they will be made aware of any SAEARs related to the tissue that they have distributed for end-use.

5.	GQ8b	Establishment staff indicated that documented risk assessments are reviewed annually, but an example was seen in which an assessment had been allocated a biennial review period. The DI is advised to ensure that the review period for each assessment is aligned with the establishment's practices and the regulatory requirement. In addition to this, a risk assessment related to vessel storage stated that vessels are stored at 2-6°C rather than the 2-8°C range specified in the establishment's procedures. The DI is advised to update this risk assessment to reflect establishment procedures.
6.	PFE3a	The establishment may occasionally store vessels for autologous use. The establishment's procedures set out a process to ensure such tissue is clearly labelled and segregated from vessels stored for allogeneic use in the storage fridge. The DI is advised to update this procedure to require staff to clearly document in the logbook that the tissue is for autologous use only. This would further ensure segregation of such tissue and capture this information in traceability records retained by the establishment following use or disposal of the tissue.
7.	PFE3d	The establishment has a defined maximum storage period of 14 days from the point of vessel procurement. During a review of the vessel logbook, examples were seen where vessels had been stored beyond their expiry date, in one case for a further eight days. The DI is advised to introduce steps to ensure vessel stocks are checked on a daily basis in accordance with establishment procedures and expired tissue is promptly disposed of.

Background

The Royal Free Hospital (the establishment) undertakes the storage, testing and distribution of arterial and venous blood vessels procured during organ retrieval from deceased adult donors. Surgeons undertaking the retrieval are commissioned by NHS Blood and Transplant (NHSBT) as part of the National Organ Retrieval Service (NORS). The NORS team may be based at the Royal Free or at another hospital within the NORS network. Donor consent, evaluation and initial serology testing are undertaken under the Organ Donation and Transplantation (ODT) framework. If vessels are not needed in reconstructive surgery for the organ recipient, they are transferred to a dedicated storage refrigerator. Serological testing of mandatory markers is repeated in accordance with the requirements of the Human

Tissue (Quality and Safety for Human Application) Regulations 2007.

The establishment has been licensed by the HTA since March 2007. This was the seventh site visit inspection; the most recent previous inspection took place in November 2017.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. However, the establishment undertook procurement of fascia rectus in response to urgent patient need in April 2019. The establishment is not licensed to undertake activities with this tissue type and was not authorised by the HTA to do so prior to activities being undertaken in this case.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

There are a total of 121 standards in the Human Application sector, and the establishment's compliance with 101 of these standards was assessed during the inspection. Standards GQ1e, PFE1d and PFE2b were not applicable. Standards GQ1t, GQ2d, PFE4b, PFE4f, PFE4l, D2b were not assessed. The 11 standards related to consent, which takes place under the ODT framework, were also not assessed during this inspection.

The establishment is also licensed for the storage of relevant material under the Human Tissue Act 2004. The establishment does not currently store any material for a scheduled purpose. Therefore, compliance with the applicable standards was not reviewed during the inspection.

Review of governance documentation

The inspection included a review of policies and procedural documents relevant to the establishment's licensable activities. The inspection also included a review of equipment service contracts, records of cleaning and servicing, temperature monitoring records, and agreements with third parties. The review of information relating to the quality management system included meeting minutes, incidents, audit records, risk assessments, job descriptions, and staff training records.

Visual inspection
During the site inspection, the inspection team visited areas for reagent and tissue storage as well as contingency storage areas.

Audit of records
The inspection team reviewed traceability records from the vessel logbook, electronic databases and vessel transfer forms as appropriate for two sets of vessels stored in the 'verified' section of the fridge, one set stored in the quarantine section at the time of the inspection, and a range of vessels used within the establishment, disposed of within the establishment and distributed to end-users for named patients.

Meetings with establishment staff
The inspection included interviews with the DI, the Persons Designated, staff involved in transplant services and clinical governance, and relevant establishment staff involved with Quality Control and Governance systems.

Report sent to DI for factual accuracy: 24 January 2020

Report returned from DI: 07 February 2020

Final report issued: 11 February 2020

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: 16 December 2022

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall (HA)

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), Human Tissue (Quality and Safety for Human Application) Regulations 2007, or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   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 number of ‘major’ shortfalls, none of which are critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   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.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a breach in the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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 and, which can be addressed by further development by the

establishment.

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 inspection.

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.