Site visit inspection report on compliance with HTA licensing standards
Inspection date: **25 September 2019**

# Anthony Nolan Cord Blood Bank

HTA licensing number 22527

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**
'E' = Establishment is licensed to carry out this activity and is 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.

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

| Site | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Anthony Nolan Cord Blood Bank** | **TPA** | **E** | **E** | **E** | **TPA** | | |

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

| Tissue Category; Tissue Type | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood** | **Authorised** | **Authorised** | **Authorised** | **Authorised** | **Authorised** | | |
| **Other; Cord Tissue** | **Authorised** | | **Authorised** | | **Authorised** | | |

**Licensed activities – Human Tissue Act 2004**

| Area | Storage of relevant material which has come from a human body for use for a scheduled purpose |
|---|---|
| **Anthony Nolan Cord Blood Bank** | **Licensed** |

**Summary of inspection findings**

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

Although the HTA found that Anthony Nolan Cord Blood Bank (the establishment) had met the majority of the HTA's standards, two minor shortfalls were found in relation to Governance and Quality System and Premises, Facilities and Equipment standards. The shortfalls were related to donor selection and records of equipment maintenance.

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.

**Compliance with HTA standards**

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

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ5 There are documented procedures for donor selection and exclusion, including donor criteria. | | |
| a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010. | The donor medical history questionnaire does not include questions regarding the ingestion of, or exposure to, substances (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health. | **Minor** |
| PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored | | |
| a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained. | The establishment could not provide the maintenance records for the controlled-rate freezers at the time of inspection. Due to the absence of records it was not possible to determine whether the equipment was maintained in accordance with the manufacturer's instructions. | **Minor** |

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.

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

| Number | Standard | Advice |
|---|---|---|
| 1. | GQ1b | The DI is advised to review procedures for all licensable activities to ensure these are up-to-date and reflect current practice. For example, the follow-up procedure for positive microbiology results from a directed donation, and the steps to take in the event of a controlled-rate freezer failure are not documented. |
| 2. | GQ1r | The DI is advised to omit staff names and contact details when updating agreements and consider using staff job titles only. This will help to ensure that agreements remain valid even if the named staff are no longer working at the establishment. |
| 3. | GQ4h | An external service provider monitors the controlled temperature storage equipment. The current terms of the agreement with this company stipulate that records will be retained for up to 30 years. The DI is advised to review the content of this agreement to ensure that raw data critical to the quality and safety of stored tissue is identified and kept for 10 years after the use, expiry date or disposal of the tissue, in line with the regulatory requirement. |
| 4. | GQ8a | The DI is advised to expand on the current risk assessments associated with the licensable activities to ensure that all risks are adequately assessed. For example, currently there is no risk assessment for the failure of the controlled-rate freezer. |
| 5. | PFE2c, PFE5f | The establishment uses a closed, sterile docking system to process the umbilical cord blood (UCB) and this equipment is cleaned after every use. However, this procedure has not been captured in the establishment's documentation for cleaning. The DI is advised to update all associated cleaning documents to ensure that all appropriate equipment is cleaned after use and this is clearly recorded. |

## Background

Anthony Nolan Cord Blood Bank has been licensed by the HTA since September 2009 for the procurement, processing, donor testing, storage and distribution of UCB under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment is also licensed for storage of relevant material under the Human Tissue Act 2004. Any UCB units not suitable for clinical use are allocated for research. The establishment also procures umbilical cord tissue (UCT), which is solely used for research.

This was the sixth site visit inspection of the establishment; the most recent previous inspection took place in September 2017. The organisation is a member of the World Marrow Donor Association (WMDA) and accredited by the Foundation for the Accreditation of Cellular Therapy and International NetCord Foundation (FACT NetCord).

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

## 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*

Out of the total 121 Human Tissue (Quality and Safety for Human Application) Regulations 2007 standards, 117 standards were assessed. The following standards were not assessed: GQ7e and GQ7f. These standards were assessed at the previous inspection. The following standards were not applicable: GQ4k and PFE1d. The standards under the HT Act 2004 were not assessed on this inspection.

*Review of governance documentation*

The inspection included a review of documentation relevant to the establishment's licensable activities. This included policies and procedural documents, agreements with third parties, risk assessments, internal and independent audits, staff training records, equipment maintenance contracts and records, reported incidents and adverse events, temperature monitoring records for storage areas, donor records, including procurement, processing and testing records.

*Visual inspection*

The visual inspection included the areas where UCB units are receipted and where initial checks are carried out, the laboratory where the quality control checks are performed, the storage areas of consumables and the clean room facility where UCB processing and storage take place.

*Audit of records*
An audit was carried out for three random maternal blood samples selected from the -80ºC freezer; these are aliquoted samples which are retained for further testing, if required. The sample details and locations were checked and verified on the electronic database. An audit was also carried out on three UCB units released for clinical use and one unit that was disposed of following a positive microbiology result. The audit for the released units covered the donor consent, maternal history questionnaire, mandatory serology results, microbiology results, dispatch sheet, temperature records, details of consumables and equipment used, photographs of the UCB unit before release, and the UCB shipment checklist form. The records for the unit destroyed following a positive microbiology result were also reviewed; these included the dispatch sheet, microbiology results, and the disposal form. There were no discrepancies were noted during the traceability audit. The records associated with the research units were not reviewed during the audit of the establishment.

*Meetings with establishment staff*
Discussions were held with the DI, who is also the Operational Manager, the Processing and Quality Control Manager, the Cord Blood Programme Quality Manager, the Head of Quality, the Clinical Midwife Advisor, the Cell and Gene Therapy Services Assistant Director and the Operational Business Manager.

**Report sent to DI for factual accuracy: 23 October 2019**

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

**Final report issued: 12 November 2019**

## 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 both the draft and 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.

## Appendix 3: HTA standards

The Human Tissue Act 2004 standards not assessed during the inspection are shown below.

**Human Tissue Act 2004 Standards**

| 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. |
| b) Where relevant, storage arrangements ensure the dignity of the deceased. |
| 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. |