

Human Tissue Authority
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Date 30 June 2010

Dear [REDACTED]

Freedom of Information request

Thank you for your request for information dated 11 June which we received as follows:

“I would like to see the following information held at HTA:

1. Site Inspection Report of Future Health Technologies of Unit 1 & Unit 10 Faraday Building, Nottingham Science & Technology Park, Nottingham, NG7 2QP.”

Response

The information you have requested can be found in the HTA Site Inspection Report dated 8 September 2009. A copy of the report is appended to this response. We believe that the absolute exemption for personal information in section 40(2) of the FOIA applies to some parts of the inspection report and have redacted this accordingly.

I would ask you to note that this report presents our findings at the time of inspection. Since this inspection was undertaken, licence conditions 4, 5, 10, 11 and 12 have been met, with the remaining conditions under review until 9 July.

Licence conditions are placed under review where the HTA has been provided with compliance information which demonstrates that an establishment has partially, but not fully, achieved compliance with a licensing standard. The HTA is able to put conditions under review to allow an establishment additional time in which to achieve full compliance with the standard in question.

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 08456 30 60 60
or 01625 54 57 45

Website: www.ico.gov.uk

There is no charge for making an appeal.

Yours sincerely

Allan Marriott-Smith
Head of Strategy and Planning



Site Inspection Report for
Future Health Technologies Ltd
Licensing number 22503

Licensed for the
procurement, testing, processing, storage, distribution and import/ export of human tissue
for human application
and the storage of relevant material for scheduled purposes

8 September 2009

Introduction

1. The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes such as research, transplantation, education and training and public display. The requirements of the HTA are set out in the Human Tissue Act 2004 (HT Act) and the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. There are supplementary requirements for those establishments storing tissue for transplantation and they are summarised in HTA Directions 001/2006.
2. The Human Tissue Authority is also the designated Competent Authority for the purposes of the European Union Tissue and Cells Directives (the Directives) so far as they relate to tissues and cells for use in human application. On 5 July 2007 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) came into force. The Regulations formally transposed the Directives into UK law. Under the Regulations the HTA regulates and licences the procurement, testing, processing, storage, distribution, import or export of tissues or cells intended for human application. The HTA has produced detailed Directions to complement the implementation of the Directives.
3. As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.
4. Under the HT Act and the Regulations, the HTA has a statutory responsibility to make judgements about the suitability of the Designated Individual, Licence Applicant (Holder), premises and practices in relation to the licensed activities. These responsibilities are set out in Part 11 and 12 of the Regulations, which is the framework for the HTA's approach to licensing and inspection.
5. The HTA must satisfy itself that the Designated Individual (DI) is a suitable person to supervise the activity to be authorised by the licence and that they will undertake the following duties:
 - secure that other persons to whom the licence applies are suitable persons to participate in the licensed activities;
 - secure that suitable practices are used in the course of carrying on the activity; and
 - secure that the conditions of the licence are complied with.
6. Designated Individuals who are licensed under the Regulations have the following additional duties:
 - secure the conditions of third party agreements, in relation to the licensed activities authorised to be carried on under his supervision; and
 - secure that the information and confidentiality requirements of Section 13 (1) are complied with.

7. The HTA must satisfy itself that the applicant for the licence is a suitable person/entity to be the holder of the licence.
8. The HTA must satisfy itself that the premises are suitable for the activity to be authorised by the licence.
9. To fulfil its statutory responsibilities, the HTA must be able to assess whether an establishment is suitable to carry out one or more of the activities regulated by the HTA. Suitability is assessed through a process of inspection. Inspections can be routine or risk based, announced or unannounced.

Inspection Process

10. HTA defines inspection as a process encompassing desk-based review, on-site assessment and analysis of relevant written, numerical, verbal and visual information to evaluate the establishment's compliance with expected standards. Desk-based reviews, described as phase one inspections, focus on the evaluation of the compliance report submitted by the Licence Applicant and Designated Individual, as well as any additional information provided by the establishment at the request of the HTA. On-site assessments, described as phase two inspections, focus on a review of the establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. Where the inspection process identifies that a standard is not being met, additional conditions may be placed on an establishment's licence to ensure that appropriate action is taken to address the non-compliance/s.
11. Both desk-based review and on-site assessments may lead to advice and guidance for improving practice in one or more areas.

Judgements

12. To enable the HTA to make effective judgements about the suitability of the DI and the Licence Holder, the suitability of the premises, the suitability of the practices taking place under the supervision of the DI and the activity or activities carried out under a third party agreement made in accordance with Directions 002/2007, the HTA standards were developed under four high-level headings:
 - Consent
 - Governance and Quality
 - Premises, Facilities and Equipment
 - Disposal
13. The evidence gathering during inspection focuses on these standards, with particular emphasis on any areas identified as requiring special attention in phase one of the inspection, as detailed above.
14. Throughout the inspection process, standards are assessed using the same four-point numerical scale used by the DI in the completion of the initial compliance report.

Numerical scale	Interpretation
1	Standard not met
2	Standard partially met
3	Standard almost met

15. The information gathered throughout the inspection process informs the HTA's licensing decisions within the regulatory framework. Where the HTA is not presented with evidence that the establishment meets the requirements of a standard/s, it works on the premise that a lack of evidence indicates non-compliance. There are varying degrees of non-compliance. The action an establishment will be required to make following the identification of a non-compliance is based on the HTA's assessment of risk to patient safety and/or tissue integrity and/or a breach of the HT Act or associated Directions.

The Inspection Report

16. The inspection report represents the findings from the evidence supplied during phase one and phase two of the inspection process, that is, from the initial compliance report, any additional documentation provided prior to the site-visit and the evidence obtained through interview and observation during the site-visit. Future inspections may identify other areas of non-compliance if new evidence is obtained. Where full compliance with a standard has been established, this is noted. Where standards have been found to be non- or partially compliant, details are included of the evidence for this finding.
17. Once the factual accuracy of the report has been agreed with the establishment, it may be published on the HTA website.

Inspection Report for Future Health Technologies

18. This report refers to the activities undertaken by Future Health Technologies Ltd (FH) HTA Licence 22503. The establishment carries out procurement, testing, processing, storage, distribution and import and export of umbilical cord blood stem cells (USCs). Stem cells stored by FH are intended for autologous use or potential directed donation to relatives.
19. In September this year FH offered a new service to store umbilical cord segments which can potentially be used to isolate mesenchymal stem cells. The MHRA informed FH that this product will not be classified as an ATMP and so all activities relating to cord segments come under the remit of the HTA. The HTA has seen a feasibility study into the isolation of mesenchymal stem cells from human umbilical cord dated 15 May 2009. Due to the recent provision of this service the HTA was not able to review data associated with any microbiological contamination of stored tissue during this phase two inspection.
20. The phase two inspection of Future Health Technologies was carried out on 8 September 2009. The inspection team comprised:
- ██████████ – HTA Regulation Manager, lead inspector
 - ██████████ – HTA Regulation Manager, support inspector
21. FH stores around 23,000 cord blood samples at its site in Nottingham. Approximately 60% of samples come from EEA states, (mainly Greece and Italy), 30% from outside the EEA and 10% from within the UK. In the UK, USCs are procured under Third Party Agreements with phlebotomists, midwives, hospitals or with individual clients. Outside the UK, agents act on behalf of FH to distribute cord blood and tissue collection kits which are used for procurement by medical staff. Once procurement has taken place, cord blood and tissue is sent to FH's main site in Nottingham for processing and storage. Cord blood is processed using the Sepax platform (Biosafe). FH has released one unit of cord blood for use.
22. Senior scientists from FH and agents who act on behalf of FH train medical staff outside the UK to procure cord blood and cord tissue.
23. All maternal blood samples sent to FH are tested at Bioiatriki Private Polyclinic Medical S.A. in Athens, Greece. Microbiology testing is done by the Doctors Laboratory, London, which is CPA accredited.

Compliance with Standards, Codes of Practice and Directions

Consent

Standard	Assessment	Score
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.	Compliance with this standard is assessed in the more detailed standards below.	
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004	The standard is partially met. Clients order cord blood and cord tissue collection kits through FH's website. FH provides literature and	2

<p>the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the HTA's Codes of Practice</p>	<p>a Stem Cell Storage Agreement for clients to sign. All procurement is carried out by third parties.</p> <p>The storage agreement covers -</p> <ul style="list-style-type: none"> • procedures followed during the collection of cord blood and cord tissue • the requirement for two series of maternal blood tests to be undertaken • mother's medical questionnaire • transport arrangements • storage conditions • release of stem cells <p>The agreement is signed by the mother, and the father, if he is willing to do so, and functions as a consent form. See advice and guidance 1.</p> <p>Clients do not need to have any discussions with an employee of FH or any individual responsible for procurement before they sign the agreement.</p> <p>Clients are however, encouraged to contact the Nottingham site of FH if they have any questions and are given information by trained personnel.</p> <p>Outside the UK, agents who act on behalf of FH, answer questions on consent, but it is not clear if these agents have been trained in local consent requirements (see condition 1).</p>	
<p>b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue Regulations 2007 and the HTA's Codes of Practice.</p>	<p>The standard is partially met.</p> <p>FH sends clients a brochure with information on consent. However, third parties in the UK who are involved in procurement may sometimes provide consent information to clients. The training and the type of information which can be provided by third parties is not documented (see condition 2 and advice and guidance 2).</p>	<p>2</p>
<p>c) The establishment or the third party's procedure on obtaining donor consent</p>	<p>The standard is fully met.</p>	<p>4</p>

includes how potential donors are identified and who is able to take consent.	The relationship between FH and clients is a commercial arrangement which is initiated by the client. Consent for donation of cord blood and tissue is taken from the mother.	
d) Consent forms comply with the HTA Codes of Practice.	The standard is almost met. See compliance under standard C1a and advice and guidance 1.	3
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.	The standard is fully met. <u>Consent forms are included in patient records which are reviewed before any sample is released.</u>	4
C2 Information about the consent process is provided and in a variety of formats.	Compliance with this standard is assessed in the more detailed standards below.	
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2006 is included.	The standard is fully met.	4
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 001/2006 is included.	The standard is almost met. Medical staff such as midwives and clinicians, and phlebotomists who are involved in procurement, may sometimes provide information on consent to clients, but no procedure details this process (see advice and guidance 2).	3
c) Information is available in suitable formats and there is access to independent interpreters when required.	The standard is fully met. The FH website provides information along with the Stem Cell Storage Agreement nine languages. Agents outside the UK are well placed to provide information in local languages.	4
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.	The standard is partially met. Staff, based in FH, who provide information to clients over the telephone receive training. However, it is not clear if personnel who are not based in the Nottingham site of FH are sufficiently trained in consent requirements. Outside the UK, agents who act on behalf of FH, answer questions on consent. However, is not clear if these agents are aware of local consent	2

	requirements (see condition 1).	
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Compliance with this standard is assessed in the more detailed standards below.	
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.	The standard is partially met. See compliance under standard C2 d and conditions 1 and 2.	2
b) Training records are kept demonstrating attendance at training on consent.	The standard is almost met. Consent training of staff based in the Nottingham site of FH is fully documented. Training records of agents, medical staff and other third parties who may be involved in the consent is not fully documented (see advice and guidance 3).	3

Governance and Quality

Standard	Assessment	Score
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Compliance with this standard is assessed in the more detailed standards below.	
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.	The standard is fully met.	4
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	The standard is partially met. FH has a range of documented procedures which cover most licensable activities. However, procedures used by third parties to procure cord blood and tissue do not include the requirement to risk assess the premises where procurement takes place (see condition 3).	2
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	The standard is fully met.	4
d) There is a document control system to ensure that changes to documents are	The standard is fully met. FH uses the Q-pulse document	4

reviewed, approved, dated and documented by an authorised person and only current documents are in use.	control system and staff can access current documents.	
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.	The standard is almost met. The Stem Cell Storage Agreement which clients sign with FH mentions that procurers may collect USCs prior to the delivery of the placenta. This is contrary to current recommendations by the Royal College of Obstetricians and Gynaecologists (see advice and guidance 4).	3
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.	The standard is not applicable.	N/A
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	The standard is partially met. FH is not able to check the name of the person who procured cord blood and tissue as it is not documented (see condition 4).	2
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.	The standard is partially met. Cord blood samples are processed on the day they are received at the Nottingham site of FH and stored in vapour phase nitrogen. The integrity of the sealed Teflon over wrap bag contributes to the system of quarantine, but this seal has not been validated (see condition 11 under standard PFE2 a). Samples which have bacterial contamination or virology positive results are moved from the original storage tank to other storage tanks. Some clients do not send maternal blood for the second series of tests. Samples which do not have these second series of donor tests (after 180 days) are removed and placed in non-conforming tanks (see advice and guidance 5). Movement of samples between tanks is authorised by senior scientists.	2
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been	The standard is fully met.	4

completed and recorded.		
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.	The standard is fully met.	4
k) There is a procedure for handling returned products.	The standard is fully met.	4
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.	The standard is fully met. FH has an agreement with CryoStore UK, to store samples.	4
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.	The standard is not applicable.	N/A
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 001/2006 and 002/2007.	The standard is partially met. Risk assessments of the premises where procurement takes place is not carried out (see condition 3). Training of personnel who carry out procurement can be improved (see advice and guidance 6).	2
o) There is a complaints system in place.	The standard is fully met.	4
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.	The standard is partially met. FH has third party agreements (TPAs) in place with procurers. However, since the name of the person who procured cord blood and tissue is not recorded, FH is not able to assure itself that TPAs are in place in all cases (see condition 5). FH has agreements in place with third parties such as couriers, the Doctors Laboratory and maintenance contractors.	2
q) There is a record of agreements established with third parties.	The standard is fully met.	4
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2007.	This standard is partially met. See conditions 2, 3, 5 and 9 and advice and guidance 2 and 7.	2

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	This standard is partially met. Many third party agreements do not specify this requirement (see condition 9).	2
t) There are procedures for the re-provision of service in an emergency.	The standard is fully met. FH has contingency arrangements with CryoStore, UK.	4
GQ2 There is a documented system of quality management and audit.	Compliance with this standard is assessed in the more detailed standards below.	
a) There is a quality management system which ensures continuous and systematic improvement.	The standard is fully met.	4
b) There is an internal audit system for all licensable activities.	The standard is fully met. Regular internal audits are carried out by the Quality Manager.	4
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The standard is not met. Independent audits are not carried out. <i>Following the inspection, Future Health Technologies put in place an agreement with Biovult to conduct independent audits. Biovult will conduct audits of Future Health Technologies every two years to verify compliance with HTA standards. Based on information provided by Future Health Technologies, the HTA is satisfied that this standard has been met and will not propose a condition on the licence.</i>	1
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.	The standard is fully met. FH carries out extensive validation and evaluation of procedures used to process cord blood and tissue. FH monitor cell recovery, cell viability and microbial contamination.	4
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Compliance with this standard is assessed in the more detailed standards below.	
a) There are clearly documented job descriptions for all staff.	The standard is fully met.	4

b) There are orientation and induction programmes for new staff.	The standard is fully met.	4
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.	The standard is fully met.	4
d) There is annual documented mandatory training (e.g. health and safety and fire).	The standard is not applicable.	N/A
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	The standard is partially met. Staff at the Nottingham site of FH are suitably trained. However, training of agents and third parties who procure or who are involved in providing information on consent is ad hoc (see conditions 1, 2 and 6).	2
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.	The standard is partially met. See compliance under GQ3e.	2
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.	The standard is fully met.	4
h) There is a system of staff appraisal.	The standard is fully met.	4
i) Where appropriate, staff are registered with a professional or statutory body.	The standard is fully met.	4
j) There are training and reference manuals available.	The standard is fully met.	4
k) The establishment is sufficiently staffed to carry out its activities.	The standard is fully met.	4
GQ4 There is a systematic and planned approach to the management of records.	Compliance with this standard is assessed in the more detailed standards below.	
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.	The standard is fully met.	4
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.	The standard is fully met.	4

c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.	The standard is fully met.	4
d) There is a system for back-up / recovery in the event of loss of computerised records.	The standard is fully met. Records are stored off site on back up tapes.	4
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.	The standard is fully met.	4
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2006, is collected and maintained.	The standard is fully met.	4
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2006 and 002/2007.	The standard is fully met.	4
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 standard is fully met.	4
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2007 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.	The standard is fully met.	4
j) Records are kept of products and material coming into contact with the tissues and / or cells.	The standard is fully met.	4
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2007.	The standard is fully met.	4
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.	The standard is fully met.	4
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.	The standard is fully met.	4

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.	Compliance with this standard is assessed in the more detailed standards below.	
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2006.	The standard is not applicable The relationship between FH and clients is a commercial arrangement which is initiated by the client.	N/A
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2006.	The standard is partially met. In most cases, clients send maternal blood samples to FH. These samples are sent from FH to Bioiatriki Private Polyclinic Medical S.A in Athens, Greece, for donor testing. Bioiatriki is not accredited as a testing centre under the EUTCD. However, FH has an SLA with Bioiatriki and has audited the laboratory. Some clients send their blood samples to hospitals in their own countries for testing and send the results to FH. FH is aware of the name of the hospitals where testing is carried out. However, FH is not aware of the accreditation status of these hospitals and does not assure itself that testing is carried out using CE marked kits or kits which meet equivalent standards (see conditions 7 and 8).	2
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.	The standard is not applicable.	N/A
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.	The standard is fully met. FH records donor test results.	4
e) Testing of donor samples is carried out using CE marked diagnostic tests.	The standard is partially met. FH is not able to assure itself that all testing is carried out using CE marked kits (see condition 7)	2
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.	This standard is fully met. Samples sent to FH comply with this standard.	4

GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.	Compliance with this standard is assessed in the more detailed standards below.	
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.	The standard is fully met. A unique identifier is used for each donation.	4
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.	The standard is partially met. An audit trail of three samples which were procured in the UK, Greece and Saudi Arabia was carried out through database records and documentation in the respective client files. The name of the procurer was not documented in all cases (see condition 4).	2
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.	The standard is almost met. End user agreements are in place. FH records the name of the transplant centre to which it distributes the tissues. The transplant details information form does not capture the name of the establishment where the transplant took place or the name of the attending clinician (see advice and guidance 8).	3
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	Compliance with this standard is assessed in the more detailed standards below.	
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The standard is partially met. The procedures for recording and investigating SAEARs within FH are appropriate. However, it is not clear if all third parties are aware of these requirements (see condition 9)	2
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.	The standard is fully met.	4
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.	The standard is fully met.	4
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or	The standard is fully met.	4

deviation from the required quality and safety standards.		
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.	The standard is fully met.	4
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.	The standard is fully met.	4
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.	The standard is fully met.	4
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.	The standard is fully met.	4
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Compliance with this standard is assessed in the more detailed standards below.	
a) There are documented risk assessments for all practices and processes.	The standard is partially met. Risk assessments take place of premises and practices at the Nottingham site of FH. However, third party premises where procurement takes place are not risk assessed (see condition 3).	2
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.	The standard is partially met. No risk assessments have been undertaken since 2007 (see condition 10).	2
c) Staff can access risk assessments and are made aware of local hazards at training.	The standard is fully met.	4
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety	The standard is not applicable. There have been no changes to donor selection criteria or processing steps which enhance the quality and safety of tissues.	N/A

of tissue and / or cells.		
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Premises, Facilities and Equipment

Standard	Assessment	Score
PFE1 The premises are fit for purpose.	Compliance with this standard is assessed in the more detailed standards below. The assessment noted below applies only to the Nottingham site of FH where processing and storage take place. The assessment does not apply to sites where procurement takes place.	
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	The standard is fully met.	4
b) There are procedures to review and maintain the safety of staff, visitors and patients.	The standard is fully met.	4
c) The premises have sufficient space for procedures to be carried out safely and efficiently.	The standard is fully met.	4
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.	The standard is not applicable.	N/A
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.	The standard is fully met.	4
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.	The standard is fully met.	4
PFE2 Environmental controls are in place to avoid potential contamination.	Compliance with this standard is assessed in the more detailed standards below.	
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.	The standard is partially met. All processed stem cells are stored together in nitrogen vapour phase, pending virology and microbiology testing. The stem cells are double bagged within a Teflon overwrap bag which is sealed. The	2

	effectiveness of the seals contributes to the system of quarantine. The thermal sealer, the setting used to seal the overwrap bag and the seals it produces are not validated (see condition 11).	
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2007.	The standard is partially met. Environmental monitoring is carried out by Queen's medical centre, Nottingham. FH monitors particle counts during the 'at rest' stage but not during 'in operation' (see condition 12). Glove prints are tested for microbial contamination after the scientist has disinfected the gloves. Hence results obtained do not reflect bacterial contamination found on gloves during processing (see advice and guidance 9).	2
c) There are procedures for cleaning and decontamination.	The standard is fully met.	4
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.	The standard is fully met.	4
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.	Compliance with this standard is assessed in the more detailed standards below.	
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	The standard is fully met.	4
b) There are systems to deal with emergencies on a 24 hour basis.	The standard is fully met.	4
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	The standard is fully met.	4
d) There is a documented, specified maximum storage period for tissues and / or cells.	The standard is not applicable. There is currently no maximum recommended storage time for cord blood stem cells and storage time is influenced by clinical need.	N/A

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.	Compliance with this standard is assessed in the more detailed standards below.	
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2006 and 002/2007.	The standard is fully met.	4
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.	The standard is fully met.	4
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.	The standard is fully met.	4
d) Records are kept of transportation and delivery.	The standard is fully met.	4
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.	The standard is almost met. USCs and cord tissue is transported in an insulated storage box which meets the requirements for transportation of biological material. A Datalogger is used to monitor the temperature of the container. A dry shipper is used to transfer frozen tissues from the processing suite to the storage area. The date and time when the dry shipper is filled with liquid nitrogen is not logged (see advice and guidance 10).	3
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.	The standard is fully met.	4
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	The standard is partially met. The temperature range and the maximum transport time are not defined (see condition 13).	2
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The standard is fully met.	4
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.	The standard is fully met.	4

j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.	The standard is fully met.	4
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	Compliance with this standard is assessed in the more detailed standards below.	
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.	The standard is fully met.	4
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The standard is fully met.	4
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.	The standard is almost met.	4
d) New and repaired equipment is validated before use and this is documented.	The standard is fully met.	4
e) There are documented agreements with maintenance companies.	The standard is fully met.	4
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	The standard is fully met.	4
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.	The standard is fully met.	4
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.	The standard is fully met.	4
i) Staff are aware of how to report an equipment problem.	The standard is fully met.	4
j) For each critical process, the materials, equipment and personnel are identified and documented.	The standard is fully met.	4
k) There are contingency plans for equipment failure.	The standard is fully met.	4

Disposal

Standard	Assessment	Score
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.	Compliance with this standard is assessed in the more detailed standards below.	
a) The disposal policy complies with HTA's Codes of Practice.	The standard is fully met. Clients are sent a success letter which details processing and test results and asked if they would wish to continue storing the cord blood sample. They are given options of either continued storage or disposal.	4
b) The disposal procedure complies with Health and Safety recommendations.	The standard is fully met.	4
c) There is a documented procedure on disposal which ensures that there is no cross contamination.	The standard is fully met.	4
D2 The reasons for disposal and the methods used are carefully documented.	Compliance with this standard is assessed in the more detailed standards below.	
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.	The standard is fully met.	4
b) Disposal arrangements reflect (where applicable) the consent given for disposal.	The standard is fully met.	4

Conclusions

24. During the inspection process, the HTA has made judgements about the suitability of the Designated Individual, the Licence Holder, the premises, and the practices taking place under the licence.

Suitability of DI and LH

25. The Designated Individual, Ms Beverley Lancashire is suitable for the role. Future Health Technologies has two persons designate who can provide operational support if required. The corporate Licence Holder, Future Health Technologies Ltd, is suitable. The corporate licence holder contact is Dr Roger Dainty who is the UK Director of FH.

Suitability of the Premises

26. The premises at the Nottingham site of FH, are appropriate for the activities carried out and provide a suitable working environment for staff.

Suitability of Practices

27. Overall, the HTA considers the practices at the Nottingham site of Future Health Technologies to be suitable for the licensed activities. The HTA finds that once cord blood samples are delivered to the site they are processed and stored appropriately. However the HTA has concerns about the agreements Future Health Technologies has with third parties who procure cord blood and tissue, and agents outside the UK who act on behalf of the company. The DI and staff working under the licence are advised to have regard to paragraphs 30 and 31 below, in order to ensure that all the relevant standards are fully met.

Summary comment

28. The HTA is satisfied that Future Health Technologies is suitable to be licensed for the procurement, testing, processing, storage, distribution and import/ export of tissues and cells and for the storage of relevant material for scheduled purposes.

Conditions (requirements) on the licence at the time of the site visit inspection.

29. No additional conditions were attached to the licence at the time of the inspection.

Conditions (requirements) related to areas of non-compliance identified during the inspection process

30. The regulatory reference is noted so the DI can refer back to relevant standards in the Human Tissue Act 2004, the Compliance Report and Directions or Codes of Practice.

No	Regulatory reference	Conditions (including reasons for conditions)
1	HTA standard: C1 a, C2 d and C3 a HTA Directions: 004/2007 paragraphs 10 and 11	<p>Condition By 1 May 2010 the DI shall ensure through SLAs, that all agents and other third parties outside the UK who act on behalf of FH receive training so that they are aware of local consent requirements. The DI shall ensure that this requirement is included in all service level agreements (SLAs) with agents and other third parties outside the UK</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason The current system of training does not ensure that all agents and third parties outside the UK who provide consent information to clients and medical staff are able to demonstrate to FH that they have been trained in local consent requirements. This condition will enable FH to comply with HTA Directions 004/2007.</p>
2	HTA standard: C2 d and C3a HTA Directions: 001/2006 paragraph 14 a, 002/2007	<p>Condition By 1 May 2010 the DI shall ensure that all procurers who may be involved in providing consent information to clients in the UK, are trained in the requirements of the HT Act, the HTA Code of Practice on Consent and HTA Directions 001/2006. The establishment should include this requirement in all third party</p>

	paragraph 118 g and h	<p>agreements (TPAs).</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>The TPAs which FH has with procurers in the UK who may be involved in providing consent information to clients does not ensure that they have received adequate training in consent. Appropriate training should include awareness of the requirements of the HT Act and the HTA Code of Practice on consent.</p>
3	<p>HTA standard: GQ1 b and GQ1 n</p> <p>HTA Directions: 001/2006 paragraph 34 g; 002/2007 paragraphs 12 k, and 118 g, h; 004/2007 paragraphs 13 b, f and g</p>	<p>Condition</p> <p>By 1 May 2010 the DI shall implement procedures to ensure that all third party procurers within the UK and outside the UK, risk assess premises where procurement takes place. The DI shall include this requirement in all agreements with third parties and should provide all procurers with a template to document risk assessments.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>Third parties who procure do not risk assess the premises where procurement takes place. This condition will enable FH to assure itself that tissues have been procured under suitable environmental conditions which ensure the quality of the cord blood and tissue and safety of the mother and baby.</p>
4	<p>HTA standard: GQ1 g and p</p> <p>HTA Directions: 001/2006 paragraph 34 d; 002/2007 paragraph 118 z; 004/2007 paragraph 13</p>	<p>Condition</p> <p>By 1 May 2010 the DI shall ensure that whenever procurement takes place in the UK or outside the UK, the name of the individual who procured cord blood and cord tissue, is provided to FH and that this requirement is included in all agreements with third parties. The DI should review the form which documents donation information so that this information can be collected.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason</p> <p>The current form does not document the name of the person responsible for procurement. This condition will ensure that FH complies with HTA Directions and will help the DI to assure herself that all persons who procure tissues have received sufficient training and are suitably qualified.</p>
5	HTA standard: GQ1 p	<p>Condition</p> <p>By 1 May 2010 the DI shall put in place a system to cross check</p>

	<p>HTA Directions: 001/2006 paragraph 34 d; 002/2007 paragraph, 8 a, 12 c</p>	<p>the name of all persons who have procured cord blood within the UK with the names of persons who can procure under a TPA with FH in order to verify the legality of the procurement process.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason FH does not have a system to determine whether or not all procurement takes place under a TPA. This system will enable FH to determine if the person who procures is working under a TPA and verify the legality of the procurement process. This condition will also enable the DI to check if the person who procures tissues has been trained and is suitably qualified.</p>
6	<p>HTA standard: GQ3 e and GQ3 f</p> <p>HTA Directions: 004/2007 paragraph 13</p>	<p>Condition By 1 May 2010 the DI shall put in place a system to assure herself that all agents and other third parties outside the UK who act on behalf of FH are suitably trained, so that they can in turn, provide training on procurement procedures to individuals who procure cord blood and tissue.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason The condition will enable the DI to assure herself that all procurement outside the UK is carried out by trained personnel and ensure compliance with HTA Directions 004/2007.</p>
7	<p>HTA standard: GQ5 b and e</p> <p>HTA Directions: 001/2006 paragraphs 25 e and f</p>	<p>Condition By 1 May 2010 the DI shall put systems in place to assure herself that donor testing of all samples is carried out in laboratories which meet standards required by the HTA Directions. These laboratories could either be accredited under the EUTCD, audited by FH or have been otherwise evaluated and shown to meet the criteria set by FH.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason Donor testing is usually carried out by Bioiatriki Private Polyclinic Medical S.A which has been audited by FH. However, clients sometimes sent their samples to other laboratories and provide donor test results to FH. This condition will ensure that FH has implemented a system to evaluate these laboratories and assure itself that all sample testing is carried out in accordance with HTA Directions.</p>
8	<p>HTA standard: GQ5a</p>	<p>Condition By 1 May 2010 the Designated Individual shall risk assess the</p>

	HTA Directions: 001/2006 paragraphs 25 e and f	<p>validity of donor test results received to date from laboratories other than Bioiatriki Private Polyclinic Medical S.A. The establishment should use the results of the risk assessments to consider whether the quarantine status of samples tested by these other laboratories should be changed in order to determine whether the relevant samples should be stored as non-conforming samples or as conforming samples.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason FH uses test results provided by laboratories other than Bioiatriki Private Polyclinic Medical S.A to determine the quarantine status of samples. This condition will ensure that the establishment risk assesses the validity of the testing done by those laboratories in order to ensure the correct quarantine status of samples.</p>
9	HTA standard: GQ7 a HTA Directions: 002/2007 paragraph 99c 004/2007 paragraph 20	<p>Condition By 1 May 2010 the Designated Individual shall ensure that all SLAs and TPAs include the requirement that FH is informed of all serious adverse events affecting or having the ability to affect the quality and safety of cord blood stem cells and tissue. The requirement includes serious adverse events which take place during procurement and testing and applies to third parties and agents of FH within the UK and outside the UK.</p> <p>Reason The requirement to inform FH of all serious adverse events which affect or have the ability to affect the quality and safety of cord blood stem cells and tissue is not stated in all SLAs and TPAs.</p>
10	HTA standard: GQ8 b	<p>Condition By 1 May 2010 the Designated Individual shall review and update risk assessments of all practices and procedures carried out at the Nottingham site of FH. Risks that may affect the quality and safety of human stem cells in cord blood and cord tissue should be addressed.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason FH has not risk assessed procedures and practices since 2007. It is a requirement that establishment review risk assessments each year or when ever changes are made to practices and procedures. FH has recently started to store cord tissue and all practices and procedures associated with this activity should be risk assessed.</p>
11	HTA standard: PFE2 a	<p>Condition By 1 May 2010 the Designated Individual shall validate the</p>

	<p>HTA Directions: 002/2007 paragraphs 43 f and g</p>	<p>sealer used to seal Teflon overwrap bags, the settings used and the seals produced, in order to ensure that an effective quarantine system is in place which prevents cross contamination of samples during storage.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason The Teflon overwrap bags help to provide the system of quarantine, as umbilical cord blood stem cells of unknown virology and bacteriology status are stored together pending test results. The sealer used to seal the Teflon bags and the seals it produces have not been validated to ensure that any risk of cross contamination is minimised.</p>
12	<p>HTA standard: PFE2 b</p> <p>HTA Directions: 002/2007 paragraphs 39 and 40</p>	<p>Condition By 1 May 2010 the Designated Individual shall ensure that in-process environmental monitoring is performed in the processing suites.</p> <p>The DI shall inform the HTA Regulation Directorate in writing when this condition is met. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.</p> <p>Reason Current environmental monitoring is only performed 'at rest'. It should also be performed when a specified number of personnel are working in the processing suite.</p>
13	<p>HTA standard: PFE4g</p> <p>HTA Directions: 001/2006 paragraph 41</p>	<p>Condition By 1 May 2010 the Designated Individual shall define and document critical transport conditions required to maintain the safety and quality of cord blood stem cells, cord tissue and the quality of maternal blood used for donor testing. The conditions should include temperature range and maximum transport time between procurement of cord blood and tissue and its receipt at FH, and in the case of maternal blood, maximum time between donor sampling and final receipt at Bioiatriki.</p> <p>Reason FH has validated the use of the Thermal Transport shipper but these studies have not been used to define critical transport conditions for transporting cord blood and tissue. This condition will help FH to determine whether suitable transport conditions have been used for each shipment in order to ensure the quality and safety of cord blood stem cells and tissue and the validity of donor test results.</p>

Advice and guidance

31. Below are matters which the HTA advises the DI to consider.

<u>No</u>	<u>Regulatory reference</u>	<u>Advice</u>
1	HTA standard:C1 a and C1 d HTA Directions: 001/2006 paragraphs 11 - 15	The DI is advised to update the Stem Cell Agreement Form when it is next reviewed so that consent is recorded on a separate consent form. The current version of the form combines both consent and contractual obligations, making it difficult for a client to distinguish between the legal requirements for consent, and the commercial agreement between client and service provider.
2	HTA standard:C1 b HTA Directions: 002/2007 paragraph 118 g	The DI is advised to document the type of information on consent which third parties in the UK can provide to clients in third party agreements.
3	HTA standard: GQ3 e and f HTA Directions: 002/2007 paragraph 28 a, b and d	The DI is advised to document all training provided by FH to all third parties including agents who act on behalf of FH and medical personnel and phlebotomists, and to record the names of the individuals who received training.
4	HTA standard:GQ1 e HTA Directions: 001/2006 paragraph 29 a 004/2007 paragraph 13 g	Procuring of cord blood <i>in-utero</i> , before the placenta is delivered is not in accordance with best practice recommendations- see Royal College of Obstetricians and Gynaecologists scientific advisory committee opinion paper 2 –Umbilical cord blood banking - http://www.rcog.org.uk/womens-health/clinical-guidance/umbilical-cord-blood-banking This practice should be risk assessed.
5	HTA standard:GQ1 h HTA Directions: 001/2006 paragraph 25 f	The DI is advised that archived plasma samples may be used for NAT testing. This will enable FH to meet the requirements for donor testing of samples which do not have the second series of donor test results. The handling and storage conditions of archived plasma should be risk assessed in order to ensure that all NAT test results obtained are accurate.
6	HTA standard:GQ1 n HTA Directions: 004/2007 paragraphs 9, 10 and 11	The DI is advised to ensure that all material imported from non EEA states complies with the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The DI is reminded that this requirement includes the need to assure herself that procurement is undertaken by suitably trained personnel.
7	HTA standard:GQ1 r HTA Directions: 002/2007 paragraph 118	The DI is advised to review all TPAs in order to ensure that they are in accordance with HTA Directions. The DI is also advised to provide a copy of the HTA Directions to all persons acting under TPAs so that they are aware of the

		requirements of the Directions.
8	HTA standard:GQ6 c HTA Directions: 002/2007 paragraph 70 c	The DI is advised to review end user forms used in end user agreements in order to capture the name of the establishment where the transplant took place or the name of the attending clinician.
9	HTA standard:PFE2b HTA Directions: 002/2007 paragraphs 39 and 40	The DI is advised to review the SOP for taking samples to monitor microbiological contamination, to ensure that glove prints are taken before gloves are disinfected by the operator.
10	HTA standard:PFE4e HTA Directions: 001/2006 paragraph 41	The DI is advised to log the time and date when the dry shipper, which is used to transfer processed cells and tissues within FH, is filled with liquid nitrogen to ensure that the required storage conditions are met.

Report sent to DI for factual accuracy: 12 October 2009

Report returned from DI: 23 October 2009

Final report issued: 24 November 2009