

Human application Compliance Report

You can apply for a licence using the online Compliance Report on the Human Tissue Authority (HTA) website www.hta.gov.uk

Please do not complete and submit this form – it is provided for reference only, to help you prepare answers to the questions.

Guidance on completing this Compliance Report and further information about licensing is available on the HTA website.

Application to be Designated Individual (DI)

Title

Forenames

Surname

If you have been known by another name, please give details

Email 1

Email 2

Telephone

Mobile

Fax

Job title

Employing body / organisation

Address of premises where licensed activity is to take place

Name of licensed establishment

Address 1

Address 2

City / town

Postcode

Activities to be licensed under the Human Tissue Act 2004 (HT Act)

- The storage of relevant material which has come from a human body, for use for Scheduled Purposes other than transplantation under the Human Tissue Act 2004

Activities to be licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

- Procurement
- Testing
- Processing
- Storage
- Distribution
- Import / export

Have you applied to be a DI for another establishment? If so, please give licensing number and establishment name

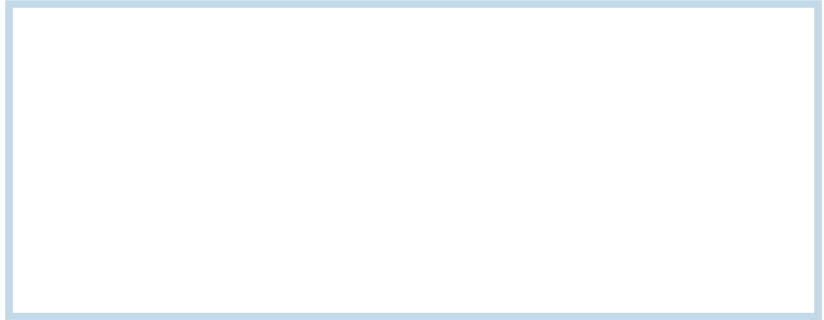
Licensing number

Establishment name

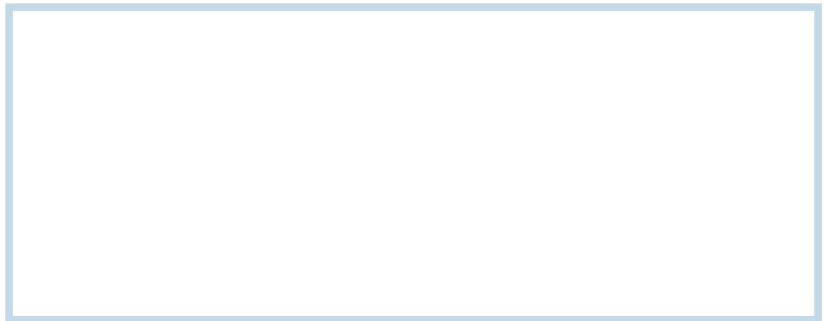
Educational or professional qualifications

Membership of relevant professional bodies (please provide registration numbers where applicable)

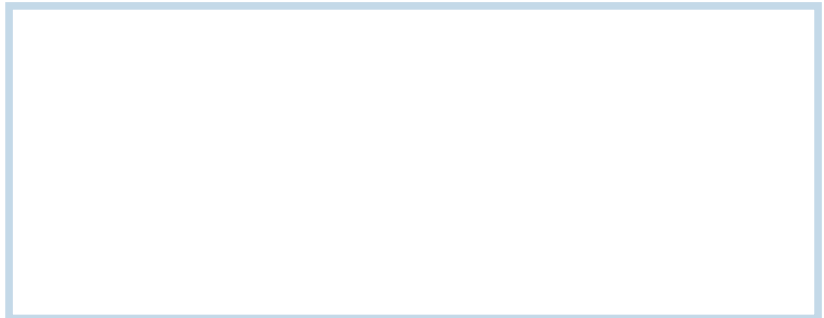
Details of any other relevant experience including managerial experience and training



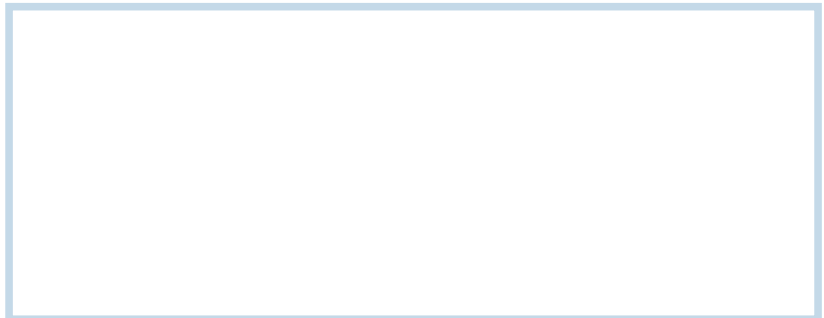
With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons working under the licence



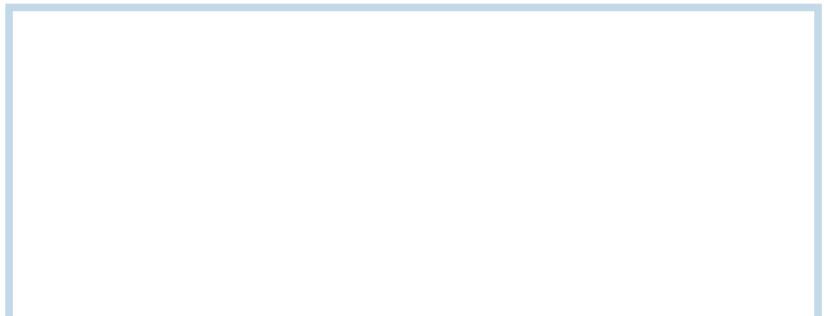
Please explain your involvement in ensuring that staff who will work under the licence are appropriately qualified and trained in techniques relevant to their work and that they are continuously updating their skills



Please explain your involvement in governance and quality management activities within the establishment



Please explain why you think you are suitable for the role of DI



Names of person(s) who have consented to be Persons Designated on the licence under the HT Act or Regulations

Do you have any satellite sites? Yes No

Do any third parties carry out procurement, processing, testing, distribution, import or export of tissues and / or cells on your behalf?

Yes No

Declaration by proposed DI

Any person making an application and submitting a compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the HT Act, the Human Tissue Authority (HTA) may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading.

I understand the terms and conditions under which a licence will be granted under the HT Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (EUTCD Regulations), particularly my duties under Section 18 of the HT Act and Regulation 12 of the EUTCD Regulations and confirm:

- a) I will follow the guidance set out in the Codes of Practice produced by the HTA and as amended from time to time; Yes No
- b) The licensed activity or activities will be carried out under my supervision; Yes No
- c) I accept that I am responsible for securing that the other persons to whom the licence applies are suitable persons to participate in the carrying on of the licensed activity or activities; Yes No
- d) I accept that I am responsible for securing that suitable practices are used by the persons under my supervision in the course of carrying on the licensed activity or activities; Yes No

- e) I accept that I am responsible for compliance with the conditions of any licence granted; Yes No
- f) I accept that I, the Licence Holder (LH) and the establishment must comply with any Directions issued by the HTA from time to time; Yes No
- g) I acknowledge that the requirements of any Directions issued by the Authority from time to time represent suitable practices in the course of carrying on the licensed activity or activities; Yes No
- h) I accept that I am responsible for compliance with the conditions of any and all third party agreements entered into by or on behalf of the LH, in relation to the licensed activity or activities authorised to be carried out under my supervision; Yes No
- i) I accept that I am responsible for securing compliance with the requirements of Regulation 13(1) of the EUTCD Regulations regarding Information and Confidentiality; Yes No
- j) The information provided is true and accurate to the best of my knowledge; and Yes No
- k) I consent to be the DI for the licence application made by the proposed Licence Holder and where applicable consent to be the Licence Holder. Yes No

Date

Satellite information

(to be completed by the Designated Individual for each satellite site)

Address of satellite premises
where activity is to take place

Name of licensed establishment

Address 1

Address 2

City / town

Postcode

Person designated at satellite

Email

Telephone

Job title

Activity to be licensed under the HT Act

- The storage of relevant material which has come from a human body, for use for Scheduled Purposes other than transplantation under the Human Tissue Act 2004

Activities to be licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

- Procurement
- Testing
- Processing
- Storage
- Distribution
- Import / Export

To assist the HTA, please provide a short synopsis describing the activities carried out at the satellite site on behalf of the establishment

Is the satellite site under the same governance as the main site?

Yes No

How does the DI intend to supervise the activities at the satellite site?

How many staff are involved in carrying out the licensable activity in the main site and in the satellite site?

Main site

Satellite site

For each tissue or cell type, how many units on average are procured, processed, stored, distributed and imported / exported by the satellite site each year?

Tissue type	<input type="text"/>
Procured	<input type="text"/>
Processed	<input type="text"/>
Stored	<input type="text"/>
Distributed	<input type="text"/>
Imported	<input type="text"/>
Exported	<input type="text"/>

Third party information

(to be completed by the Designated Individual for each third party agreement)

Is there an agreement in place with the third party?

Yes No

What was the start date of the agreement?

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Does the agreement have an end date?

Yes No

How often is the agreement reviewed?

Address of third party premises
where activity/ies takes place

Organisation

Department

Address 1

Address 2

City / town

Postcode

Name of third party contact

Job title

Email

Telephone

Activity/ies relating to tissues and / or cells for human application taking place under the third party agreement

- Procurement
- Testing
- Processing
- Distribution
- Import / Export

Is the establishment licensed by the HTA for the activity/ies it carries out on your behalf?

- Yes, please state HTA licensing number and do not answer the third party questions below

Licensing number

- No (answer questions below)

Is the third party carrying out the activity/ies on behalf of the establishment accredited?

Procurement

JACIE accreditation

Date of accreditation

Date of last reaccreditation

Testing

CPA accreditation

Date of accreditation

Date of last reaccreditation

CPA conditional accreditation

Date of conditional accreditation

Processing

JACIE accreditation

Date of accreditation

Date of last reaccreditation

CPA accreditation

Date of accreditation

Date of last reaccreditation

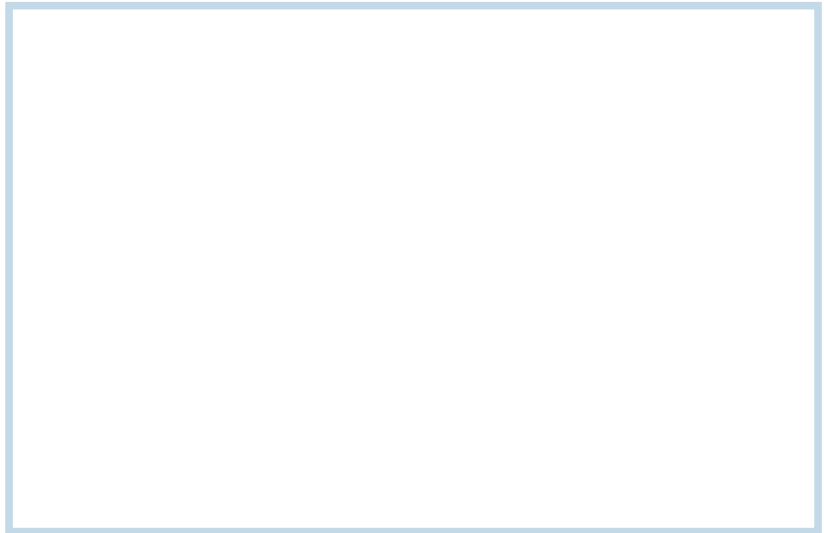
CPA conditional accreditation

Date of conditional accreditation

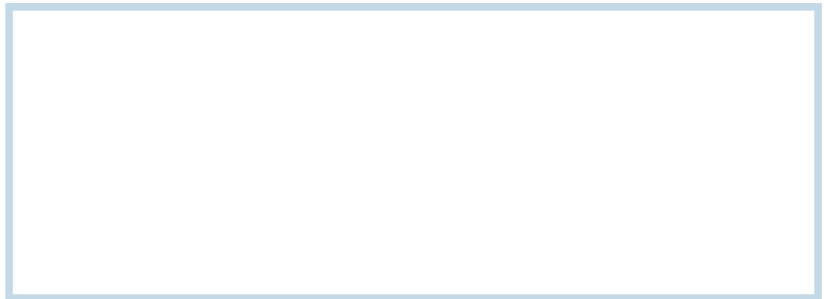
Other accreditation

– please give the date of accreditation and reaccreditation where appropriate and detail how the accreditation relates to the licensed activity

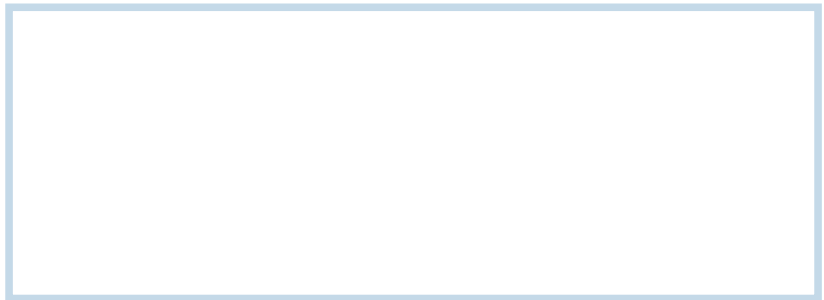
To assist the HTA, please provide a short synopsis describing the activities carried out at the third party premises on behalf of the establishment



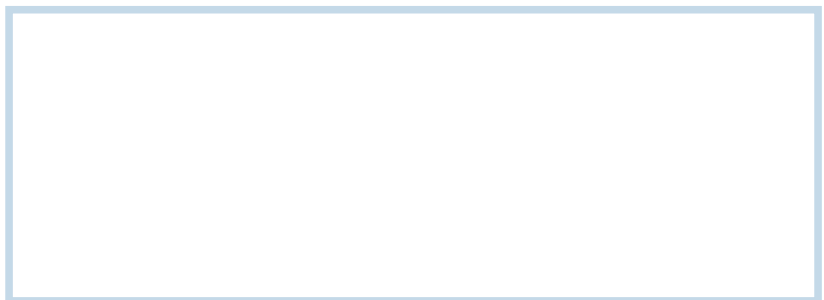
How have you assured yourself that the third party premises are fit for purpose?



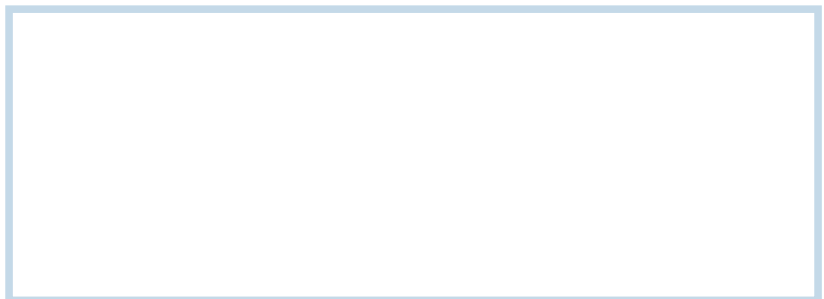
Does the third party agreement specify the minimum requirements for the validation and maintenance of equipment?



Does the third party agreement ensure that the third party has procedures for all aspects of the activity they are carrying out?



Does the third party agreement ensure that traceability from donor to recipient is maintained?



If the third party has access to patient records, is there a system to ensure confidentiality?

What system is there to ensure that the third party reports serious adverse events or reactions to the establishment and the HTA?

What systems are there to ensure that the third party could recall any tissues and / or cells if required?

If the third party is importing on behalf of the establishment how does it ensure that the tissues and / or cells meet the HTA's standards on quality and safety of tissues and cells?

If the third party is transporting material on behalf of the establishment how does it ensure that the tissues and / or cells are maintained under the correct conditions?

What arrangements are there for the third party to provide information on the number and types of tissues and / or cells it is procuring, testing, processing, distributing or importing / exporting on behalf of the establishment?

Corporate Licence Holder Application

Full name of body

Trading name / business name
if different from name of body
above

Type of corporate body

- Limited Company
- Sole Proprietor
- Public Limited Company
- Partnership
- Charity
- NHS Organisation
- Other Public Body, please describe

- Higher Education Institution
- Other, please describe

Please provide:

If a Private / Public / Limited Company
Co. Registered No.

If a sole proprietor
Name and address

If a charity
Charities Registered No.

If partnership
Names and addresses of partners

Other
Trading / Business Address

Name and registered office of
parent company, if any

If the body has been known by
another name in the past five
years please give details

Name of person authorised to sign
on behalf of the corporate body

Job title

Correspondence address if different
from the licensed premises

Organisation name

Department

Address 1

Address 2

City / town

Postcode

Email 1

Email 2

Telephone

Fax

Please explain why the corporate
body is suitable for the role of
Licence Holder

Declaration by the Corporate Applicant

Any person completing this application and compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the HT Act 2004, the HTA may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading.

On behalf of the corporate body I accept the terms and conditions under which licences will be granted under the HT Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (EUTCD Regulations), and confirm:

- a) The information provided is true and accurate Yes No
- b) The DI has consented to this application Yes No
- c) I have been authorised to make this application on behalf of the applicant Yes No
- d) I accept that the Licence Holder is responsible, under the EUTCD Regulations, for entering into a third party agreement, with any third parties that procure, test, process, distribute, import or export tissues and / or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and / or cells; Yes No
- e) I accept that the Licence Holder, the DI and the establishment must comply with any Directions issued by the HTA from time to time; and Yes No
- f) I, on behalf of the Licence Holder, acknowledge that the requirements of any Directions issued by the HTA from time to time represent suitable practices in the course of carrying on the licensed activity or activities. Yes No

Date

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Application to be Licence Holder (If different from DI)

Title

Forenames

Surname

If you have been known by another name, please give details

Email 1

Email 2

Telephone

Fax

Correspondence address if different from licensed premises

Organisation

Department

Address 1

Address 2

City / town

Postcode

Job title

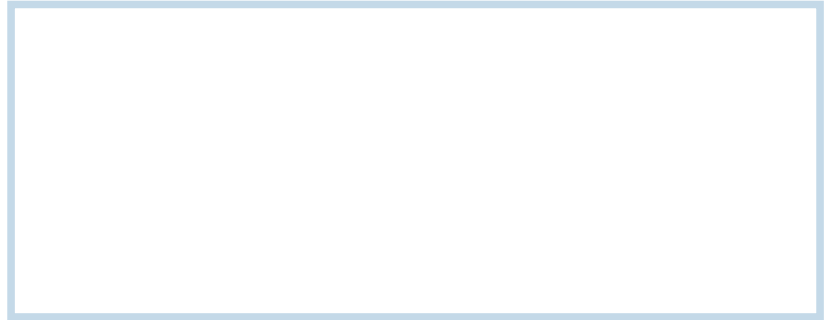
Employing body / organisation

Educational or professional qualifications

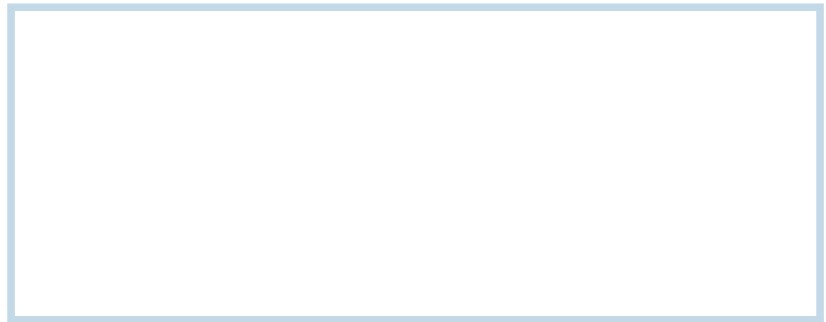
Membership of relevant professional and / or statutory bodies (please provide registration numbers where applicable)



Details of any other relevant professional experience including managerial experience and training



Please state why you think you are suitable to be the Licence Holder



Declaration by the applicant

Any person making an application and submitting a compliance report should be aware that under paragraph 7(2)(a) of Schedule 3 of the HT Act 2004, the HTA may revoke a licence if it is satisfied that any information given for the purposes of the application for a licence was in any material respect false and misleading.

I understand the terms and conditions under which a licence will be granted under the HT Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (EUTCD Regulations), and confirm

- a) The information provided is true and accurate Yes No
- b) The DI has consented to this application Yes No
- c) I accept that the licence holder is responsible, under the EUTCD Regulations, for entering into a third party agreement, with any third parties that procure, test, process, distribute, import or export tissues and / or cells for human application on behalf of the establishment, or supply any goods or services which may affect the quality or safety of tissues and / or cells; Yes No
- d) I accept that I, the DI and the establishment must comply with any Directions issued by the HTA from time to time; and Yes No
- e) I acknowledge that the requirements of any Directions issued by the Authority from time to time represent suitable practices in the course of carrying on the licensed activity or activities. Yes No

Date

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Establishment information

Has your establishment already received an HTA licensing number?

Yes – please enter the licensing number

Licensing number

No

What is the range of tissues and / or cells procured, processed, stored, distributed, imported and exported?

- Pericardium
- Arterial vessels
- Other cardiovascular
- Bone
- Tendons
- Meniscus
- Skin
- Cornea
- Sclera
- Ocular limbal stem cells
- Amnion
- Bone marrow
- Peripheral blood stem cells
- Cord blood
- Donor lymphocyte infusions
- Other stem cells
- Stem cell lines
- Other _____

Is the establishment responsible for donor selection?

Yes No

Is the establishment responsible for obtaining consent?

Yes No

Is the establishment an end user of the tissue and / or cells?

Yes No

- Distribution
- Local
 - Regional
 - National
 - European Economic Area (EEA) states
 - Non EEA states

Are you storing relevant material for research? If so please give a brief synopsis of what material is held, and who is using the material.

For each tissue or cell type how many units on average are procured, processed, stored, distributed and imported / exported each year?

Tissue type

Procured

Processed

Stored

Distributed

Imported

Exported

For testing establishments, how many samples on average are tested each year?

To assist the HTA, please provide a synopsis describing

- the activities taking place
- how long the activities have been taking place
- how the facility is used
- how the facility relates or interacts with other establishments.

If possible, please include a floor plan which shows where the activity to be licensed takes place

Please document and describe any serious adverse events or reactions that have occurred in your establishment between April 2006 and April 2007

Serious adverse events

Serious adverse reactions

Information about inspection and accreditation

Does the establishment have any form of accreditation?

Yes No

If YES give the date of the accreditation and some information about the activities covered by the accreditation:

Accredited JACIE

Date of current valid accreditation

Accredited CPA

Date of current valid accreditation

Conditional accreditation CPA

Date of current valid accreditation

Accredited ISO / 9000

Date of current valid accreditation

Accredited Investors in People

Date of current valid accreditation

D	D	M	M	Y	Y
---	---	---	---	---	---

Other

Date of current valid accreditation

D	D	M	M	Y	Y
---	---	---	---	---	---

If accredited, please explain how the licensable activities are covered by this accreditation

HTA Standards

Consent

C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue Regulations 2007 and as set out in the HTA's Codes of Practice.

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 Human Tissue Regulations 2007 and the HTA's Codes of Practice.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

Standard is only partially met – please explain why and what action is being taken to meet the standard in full?

(On the online application form you will be asked to provide text for all of the standards below which you have only partially met).

(250 words max)

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) Consent forms comply with the HTA Codes of Practice.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

C2 Information about the consent process is provided and in a variety of formats.

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) Information is available in suitable formats and there is access to independent interpreters when required.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) Training records are kept demonstrating attendance at training on consent.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

Estimated time to complete 20 minutes
--

Actual time to complete

Governance and quality systems

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.

a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) There are procedures for all licensable activities that ensure integrity of tissues and / or cells and minimise the risk of contamination.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

e) There are procedures for tissues and / or cell procurement, which ensure the safety of living donors.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

k) There is a procedure for handling returned products.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

o) There is a complaints system in place.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

q) There is a record of agreements established with third parties.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2007.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

t) There are procedures for the re-provision of service in an emergency.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

GQ2 There is a documented system of quality management and audit.

a) There is a quality management system which ensures continuous and systematic improvement.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) There is an internal audit system for all licensable activities.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

a) There are clearly documented job descriptions for all staff.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) There are orientation and induction programmes for new staff.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There is annual documented mandatory training (e.g. health and safety and fire).

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

e) Personnel are trained in all tasks relevant to their work and their competence is recorded.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

h) There is a system of staff appraisal.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

i) Where appropriate, staff are registered with a professional or statutory body.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

j) There are training and reference manuals available.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

k) The establishment is sufficiently staffed to carry out its activities.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There is a system for back-up / recovery in the event of loss of computerised records.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

f) There are procedures to ensure that donor documentation, as specified by Directions 001/2006, is collected and maintained.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

j) Records are kept of products and material coming into contact with the tissues and / or cells.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2007.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

m) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

n) 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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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 001/2006 .

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

e) Testing of donor samples is carried out using CE marked diagnostic tests.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

f) Samples taken for testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

GQ6 A coding and records system facilitates traceability of tissues and cells, ensuring a robust audit trail.

a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.

a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.

a) There are documented risk assessments for all practices and processes.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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 / or cells.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) Staff can access risk assessments and are made aware of local hazards at training.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- 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 of tissue and / or cells

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

Estimated time to complete
90 minutes

Actual time to complete

Premises, facilities and equipment

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- b) There are procedures to review and maintain the safety of staff, visitors and patients.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- c) The premises have sufficient space for procedures to be carried out safely and efficiently.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- e) There are procedures to ensure that the premises are secure and confidentiality is maintained.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

- 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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

PFE2 Environmental controls are in place to avoid potential contamination.

a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) There are procedures for cleaning and decontamination.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

PFE3 There are appropriate facilities for the storage of tissues and 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

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) There are systems to deal with emergencies on a 24 hour basis.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) There is a documented, specified maximum storage period for tissues and / or cells.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to their destination.

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) Records are kept of transportation and delivery.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

g) Critical transport conditions required to maintain the properties of tissues and / or cells are defined and documented.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

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.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

d) New and repaired equipment is validated before use and this is documented.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

e) There are documented agreements with maintenance companies.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

g) Instruments and devices used for procurement are sterile, validated and regularly maintained.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

i) Staff are aware of how to report an equipment problem.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

j) For each critical process, the materials, equipment and personnel are identified and documented.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

k) There are contingency plans for equipment failure.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

Estimated time to complete
25 minutes

Actual time to complete

Disposal

D1 There is a clear and sensitive policy for disposing of tissues and cells.

a) The disposal policy complies with HTA's Codes of Practice.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) The disposal procedure complies with Health and Safety recommendations.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

c) There is a documented procedure on disposal which ensures that there is no cross contamination.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

D2 The reasons for disposal and the methods used are carefully documented.

a) There is a procedure for tracking the disposal of tissues and / or cells that details the method and reason for disposal.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Self-assessment rating				
1	2	3	4	N/A

HTA rating				
1	2	3	4	N/A

Estimated time to complete
15 minutes

Actual time to complete