Site visit inspection report on compliance with HTA licensing standards

John Radcliffe Hospital

HTA licensing number 12217

Licensed under the Human Tissue Act 2004 for the

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

10-12 April 2017
2-5 May 2017

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

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

Although the HTA found that John Radcliffe Hospital had met some of the HTA's standards, several major and minor shortfalls were found across the range of standards. Major shortfalls were found against Consent, Governance and quality systems and Traceability standards. In addition, the inspection process identified several areas and episodes of tissue storage that should have been under the governance of the licence but were not.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004 (HT Act). They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out by the University of Oxford at John Radcliffe Hospital (the establishment). The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose under the HT Act. The licence covers the premises at John Radcliffe Hospital (hub site) and three satellite sites: Nuffield Orthopaedic Centre; The Churchill Hospital; and Department of Pharmacology (in the University's Medical Sciences Division). The hub site for the licence, the John Radcliffe Hospital, houses collections within the Nuffield Division of Clinical Laboratory Sciences (NDCLS), the Nuffield Department of Medicine, the Nuffield Department of Obstetrics and Gynaecology, and the Nuffield Department of Surgical Sciences (NDSS). These sites encompass various activities at the University of Oxford and the Oxford University Hospitals NHS Foundation Trust (OUH).

The establishment has been licensed by the HTA since 2007 and was last inspected by the HTA in June 2012. Since the last inspection, the establishment has significantly increased the number of sample collections stored under the licence. The Department of Pharmacology became a satellite site of this licence in 2013. The establishment was licensed previously under the name 'Oxford Radcliffe Biobank', but the establishment changed this to 'John Radcliffe Hospital' in 2015, to reflect the wider collections of samples stored under the licence. The licence previously included an additional satellite site, the Cowley Store, until this satellite site licence was revoked in February 2017 when all relevant material stored under the licence at this site was disposed of or transferred to other premises covered by the establishment's licence.

The establishment stores human samples for use for the scheduled purposes of 'research in connection with disorders, or the functioning, of the human body'; and 'education or training relating to human health'. A large number of sample collections are stored under the licence. At the time of the inspection, there were 35 sample collections stored under the licence.

The DI, who took on this responsibility around two years ago, has introduced a number of changes to the procedures relating to human samples at the establishment, to improve oversight and governance. The DI is supported by a Governance Manager, and an additional staff member is due to commence work in a similar role in the coming months. The establishment has at least one Person Designated (PD) for each collection stored under the licence.

The establishment has set up a system for groups to register collections to be stored under the licence. The establishment has made this information available to groups working at the establishment and relies on individual groups declaring their samples and registering them with the DI. The DI has strengthened the establishment's registration system by reviewing the system of audit of collections at the time of registration. Although the DI has made significant efforts to ensure that all sample collections at the establishment subject to the licensing requirements of the HT Act are stored under the licence, a number of sample collections have been stored at the establishment outside the governance of the licence and potentially some collections still remain outside the governance of the licence. This demonstrates that the DI does not have sufficient oversight of all relevant sample collections.

The establishment has overarching policies and standard operating procedures (SOPs) for collections held under the licence, and each group is expected to have SOPs and risk assessments specific to their work under the licence (see shortfalls against standards GQ1(a), GQ1(b), GQ6(a), GQ6(b), and GQ6(c)).

Each group is responsible for maintaining traceability records for their sample collections. The establishment's procedures require that all samples stored under the licence are assigned a unique identification number or name, which is used to track sample receipt, storage, use, distribution and disposal. Each group uses their own databases and procedures to record sample traceability. Where samples are disposed of, this is by incineration and each group keeps records of disposal.

Research collections

At the time of the inspection, samples were being stored under the licence as part of seven research tissue banks (RTBs) which have received generic ethical approval from recognised research ethics committees (RECs). These RTBs are: Oxford Radcliffe Biobank (ORB); Oxford Musculoskeletal Biobank (OMB); Quality in Organ Donation (QUOD); Oxford Transplant Biobank (OTB); GI Illness Biobank; Oxford Vaccines Group Biobank (OVB); and Oxford Brain Bank (OBB) (numbers 09/H0606/5+5, 09/H0606/11, 13/NW/0017, 14/SC/1211, 11/YH0020, 10/H0504/25, and 15/SC/0639 respectively).

The establishment also stores other sample collections under the licence for use for research. These samples are from projects with no, or expired, ethical approval from a recognised REC. Some of these are legacy collections, which are archived and are no longer being

added to, but are available for use for research. A number of these samples are ‘existing holdings’ (held prior to the HT Act coming into force on 1 September 2006), and are thereby exempt from the HT Act consent requirements.

The establishment also stores samples of relevant material for use for research projects which have received approval from a recognised REC, thereby exempting storage of these samples from the HT Act licensing requirements. The establishment’s systems relating to the storage and use of this material were not assessed as part of this inspection. The University’s Clinical Trials and Research Governance (CTRG) Office are responsible for maintaining oversight of REC approval, but it is not currently responsible for ensuring that where approval expires, or samples are stored outside the terms of the approval, relevant material is stored under the licence. This responsibility is considered to rest with the researcher.

The establishment also stores human samples for research which have been processed to render them acellular. Acellular samples are not relevant material and are thereby not subject to the HT Act licensing requirements, and were not included in the scope of this inspection.

Education and training collections

The establishment stores two collections under the licence for use for education or training; these are the pathology pot collection and surgical skills collections.

The pathology pot collection of preserved tissues and organs is used in teaching sessions as part of courses run by the University. These samples are ‘existing holdings’, and are thereby exempt from the HT Act consent requirements. The samples are stored and used at the John Radcliffe Hospital site (the hub site).

The Oxford Orthopaedic Simulation and Education Centre (OOSEC), which contains a surgical skills lab, stores and uses cadaveric material as part of surgical skills training courses run at the establishment. The samples are sourced from commercial suppliers. The inspection process identified a period spanning two years when licensable activities took place outside of the governance of any HTA licence (please see ‘Inspection findings’ under GQ5(b))

Description of inspection activities undertaken

The last inspection of this establishment took place in June 2012. This report describes the second, routine site visit inspection of this establishment. This is the first inspection of the establishment against the new HTA standards that came in to force on the 3 April 2017. The inspection took place on 10-12 April 2017. Due to the significant concerns identified during this inspection, the HTA returned to the establishment on 2-5 May 2017 to continue the inspection and audit every collection stored under the licence.

The inspection included visual inspection of each of the four sites covered by the licence. At each site, the inspection also included interviews with key members of staff working under the licence and an extensive review of documentation relevant to each group's activities. The inspection included all research collections which were declared to the HTA as being stored under the licence at all of the sites covered by the HTA licence. This includes collections stored at: Nuffield Department of Medicine Research Building (NDMRB); Kennedy Institute; Churchill Hospital Cancer Centre; Oxford Respiratory Trials Unit (ORTU); Nuffield Department of Obstetrics and Gynaecology (NDOG); Weatherall Institute of Molecular Medicine (Oncology laboratory); and Department of Pharmacology.

An audit of samples and records was conducted at each site and for every collection held under the licence, including multiple audits for each RTB. A variety of storage arrangements were also inspected during the audit, including storage at: room temperature (of formalin-fixed paraffin-embedded (FFPE) samples and tissue sections on microscope slides); and frozen storage in -20 °C and -80 °C freezers and liquid nitrogen tanks. In total, 205 samples were traced from storage to records or vice versa, consisting of a range of relevant material stored under the licence including samples of: whole blood; buffy coat; peripheral blood mononucleocytes (PBMCs); endometrium; ovary; lung; breast; kidney; kidney stones; bladder; brain; tumour biopsies; and tissue arrays. Disposal records were also audited. Anomalies found during these audits are documented in the 'Inspection findings' section of this report.

The inspection process has identified several collections of tissue that should have been under the governance of the licence but were not, including expired clinical trials (e.g. VIDEO at Nuffield Orthopaedic Centre) and a large amount of existing holdings. Related to this finding, a significant number of staff working under the licence demonstrated a lack of understanding of the licensing and consent requirements of the HT Act (see shortfall against

standard GQ3a). In addition, a number of uncatalogued collections are being held under the licence and are detailed in the 'Inspection findings' section of this report (see shortfalls against standard T1(c).

Inspection findings

Although the HTA found the Licence Holder, the Designated Individual and the premises to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of significant concern. With regard to the DI, although she is deemed to be a suitable person and it is recognised that several issues had their origin under the oversight of the previous DI, the HTA believes that she has not yet ensured that suitable practices are used in the course of conducting activity under the licence. The HTA will monitor progress on this through the Corrective and Preventative plan to be completed by the establishment (see below).

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	The establishment could not evidence consent for the storage of a number of samples in various collections stored under the licence: • ORB053 (OSPREA/Gynaecology) – multiple samples stored with no record of consent; • ORB048 (ORTU) – in excess of 1000 samples from an expired clinical trial which have been stored for longer than consent has been given; and • ORB002 (TMA collection) – one sample found with no record of consent which had been released to a researcher and then recalled and has since been disposed of. All associated samples in the TMA	**Major**

	block from this donor have been disposed of. • ORB 036 (C02.356 - 'in-vitro study of the immune response to serex antigens associated with diffuse large B cell lymphoma''). A study specific consent form could not be found in the medical notes. The establishment was also storing samples intended for research use where consent for use for research had been declined: • ORB015/ORB016 (Cancer Centre) – one sample was stored for use for research where consent had been declined. This sample has been disposed of and was not used in research. The establishment cannot therefore provide assurance that valid and appropriate consent has been obtained for the storage and use of all samples in accordance with the requirements of the HT Act for all samples stored under the licence.	
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.	The establishment does not have consent records readily available to those using or releasing relevant material. Although the establishment does have a consent tracker spreadsheet, a large number of consent forms for samples stored under the licence could not be provided to the HTA during the inspection and were submitted to the HTA sometime following the inspection. The establishment cannot therefore assure themselves that valid and appropriate consent has been obtained for the storage and use of samples in accordance with the requirements of the HT Act for all samples stored under the licence. *Refer to Advice, item 2.*	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of	The staff member in the Department of Pharmacology who sought consent for the storage and use of blood samples from staff volunteers had received no training in consent requirements of the HT Act.	**Minor**

the HT Act and the HTA's Codes of Practice.	Although this activity has now ceased and the samples have been disposed of, the samples were stored under the licence for a significant period of time and were being stored at the time of the inspection. A number of researchers in NDOG have obtained blood samples from staff volunteers without consent training or documenting the consent taken. This activity has also ceased.	
b) Records demonstrate up-to-date staff training.	There were a lack of records demonstrating up-to-date staff training.	**Minor**

Governance and Quality

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Whilst the central governance of the biobank includes policies and procedures, SOPs are not in place for all of the research groups storing samples under the licence and procedures vary widely between groups. SOPs are fundamental to ensuring that licensed activities are undertaken consistently, in accordance with regulatory requirements. Where SOPs are in place, staff at the establishment have not always acknowledged and signed a new/amended SOP, as per the establishment's procedure. In addition, staff at the establishment have not always acknowledged and signed a new/amended SOP, as per the establishment's procedure. The establishment cannot therefore not provide assurance that activities are conducted in accordance with the regulatory requirements.	**Major**
b) There is a document control system.	A number of documents have no document control information.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Audits are not undertaken regularly across all collections with several audits undertaken immediately in advance of the inspection. As demonstrated by the inspection findings, current audit arrangements are not sufficient to provide adequate assurances across the whole range of the material stored under the governance of the licence.	**Minor**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	Although audit records are available for several research groups storing samples under the licence, records alone of audits are not sufficient and do not always include details of what the audit comprised of or the actions that were taken. Not all audits include details of preventative actions, where they would be required and there are no records of follow up actions for some audits. The establishment cannot therefore evidence that appropriate corrective and preventative actions have been taken to address audit findings.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
a) Qualifications of staff and all training are recorded, records showing attendance at training.	Not all staff working under the licence have received training in the HT Act, HTA Codes of Practice and local procedures, leading to a patchy and inconsistent picture. A number of staff working under the licence demonstrated a poor knowledge of regulatory requirements, including the consent requirements, and /or internal policies and procedures. This has contributed to the situation where a number of collections have incorrectly fallen outside of the governance of the licence for several research groups and research collections.	**Major**
GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	There is inconsistency in incident reporting. Staff do not always adhere to the establishment's procedure for reporting incidents within four days.	**Minor**

b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.	A number of serious incidents/adverse events have remained open and un-actioned for extended periods of time. These incidents have included licensing breaches with regards to premises and breaches related to unregistered collections and consent. Incident reports do not all include details of corrective and preventative actions, where they would be required. The establishment cannot therefore evidence that appropriate corrective and preventative actions have been taken in response to all incidents. Adverse events are neither reported or investigated promptly: • Adverse Event_ 92 OOSEC Breaches occurred between September 2011-June 2013 when a number of surgical skills courses storing cadaveric material were undertaken at the NOC site. These licensable activities took place outside of the governance of any HTA licence. These matters were not reported internally until December 2016. • Adverse Event_93 ORB063 Discovered 13/07/16 and not logged as an AE until 2017 Some adverse events were reported following the inspection for the first time: • Adverse Event_100 Unregistered collection of 1888 samples collected up to 1 August 2007 and were not registered under the governance of the HTA licence until added on 6th June 2016. The breach occurred from the date that the end of study notification was submitted to REC (which is unknown to the establishment) and the collection has now been disposed of. • Adverse Event_104 NDOG Samples of PBMC from one staff volunteer were being stored with only Central University Research Ethics Committee (CUREC) approval and were not under the governance of the HTA licence. CUREC is not a recognised REC and these samples have been disposed of.	**Major**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	A number of groups working under the licence do not have risk assessments relating to compliance with the HT Act and HTA's Codes of Practice. Where risk assessments are present, many do not cover all practices and processes requiring compliance with the HT Act and HTA's Codes of Practice, and many do not include sufficient details of the risks and mitigating actions.	**Minor**
b) Risk assessments are reviewed regularly.	Where risk assessments are in place, many are not reviewed regularly.	**Minor**
c) Staff can access risk assessments and are made aware of risks during training.	Where risk assessments are in place, it is unclear if staff have access to them or are informed of these risks during any staff training. Many staff demonstrated a lack of awareness of the establishment's risk assessments relating to activities conducted under the licence.	**Minor**

Traceability

Standard	**Inspection findings**	**Level of shortfall**
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	The sample traceability processes for some research groups are not sufficiently robust and some groups had difficulty demonstrating full traceability of samples during the HTA audit. • Not all samples have unique identifiers. For several sample collections, aliquots of samples from the same participant are labelled with the same identification code. The establishment attempts to maintain traceability of these samples by recording the number of aliquots; however, some databases did not clearly record the number of sample aliquots remaining and the fate of the	**Minor**

	used/disposed of samples. • Some samples have handwritten labels, which are smudged and difficult to decipher.	
b) A register of donated material, and the associated products where relevant, is maintained.	Sample traceability databases need to ensure they are appropriate for use and are supported with technical support, where required, particularly in relation to the ORB RTB. Sample traceability systems and databases vary considerably, even within the same group, and some groups use several different databases for traceability of samples, which can lead to loss of traceability, especially where the establishment does not have documented procedures detailing the use of the different sample databases (e.g. Cancer Centre).	**Minor**
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	Several partly or completely uncatalogued collections were found during the inspection, some of which had been identified by the establishment: • ORB063 is a large collection of uncatalogued samples consisting of slides, tissue blocks and frozen material which are in the process of being catalogued. • 42 uncatalogued bronchial samples were found in the sample handling lab (Churchill Hospital). Disposed of on 18/04/2017. • 489 uncatalogued frozen samples (existed holdings) were discovered in the WIMM consisting of normal and tumorous bladder/kidney samples have now been disposed of. • 2235 samples in NDOG compared to the 1205 originally declared. This may include uncatalogued samples in the freezer. • NDMRB Adverse Event (AE_89) Reported by Kessler group. Listed samples of buffy coat not previously registered under HTA licence • Uncatalogued research slides within NDCLS thought to be existed holdings, which were found and declared after the visit and are to be disposed of.	**Major**

	• Risk Management Committee of licence 12217: January 2017 matters covered: - ORB001 Breast collection- 1500 samples not on any sample inventory "Specimen inventory found to be below standards upon audit" - ORB063 Fixed tissue "stored on licensed premises but not registered" • Traceability audits were performed on 205 samples. Discrepancies in traceability were identified and include: - ORB036 Two sample discrepancies. One sample in storage was in a different position to that recorded on the database. One sample in storage was recorded on the database as having been used. - ORB036 Some of these samples were contained in tower 21 (Pippin LN tank) which was labelled as containing only samples from ORB017 - ORB036 Original consent form for one sample pre-dated ORB ethics; it was not found in the medical notes and no investigator file was ever kept. - ORB002 (TMA) 70 blocks currently in quarantine whilst consent checks are performed. Each block contains samples from multiple patients. One sample found with no record of consent and have been disposed of. • As a result of the findings of the inspection, several risks that can have a significant impact on sample traceability have been identified and these should be formally assessed. These risks include but	

	are not limited to: - Samples deleted from databases upon use (ORB055 NDMRB) - Use of samples not recorded for all collections (ORB055 NDMRB) - Uncatalogued collections (ORB063)	
T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	Records of sample disposal do not always include date, reason for disposal and method used. SOPs for disposal do not always state that date, reason for disposal and method must be recorded. In addition, there were groups who could not evidence records of disposal during the inspection (e.g. NDMRB).	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	The establishment has relied on the storage of a large number of consent forms within the patients' medical notes. This has meant that they are not available when needed due to archiving of the notes. The DI is advised to consider a more effective way to evidence consent.
2.	GQ1(a)	The DI is advised that documentation across the establishment needs to be updated to reflect the new codes and standards for the research sector that came into force on 3 April 2017
3.	GQ1(b)	For QUOD documentation, consistent document control processes are needed, specifically approval dates for documents, as some documents have several approval dates on the front of them.
4.	GQ1(b)	The DI is advised to ensure all printed databases have document control (e.g. date printed) to assist staff in knowing whether these printed documents are the most up to date versions.
5.	GQ1(b)	There is an inconsistent approach to written amendments of documents, including key documents for evidencing compliance with the HTA Codes of Practice.

6.	GQ1(b)	The DI is advised to ensure that documents are written and approved by different people
7.	GQ2(a)	The DI is advised to review annual audits to include more detailed questions about documentation especially risk assessments as this had been recognised as a potential weakness.
8.	GQ2(b)	The DI is advised to encourage sharing of audit findings in each research group to increase awareness and future learning.
9.	T1(c)	The DI is advised to consider labelling all storage units to indicate that they contain human tissue samples stored under the licence and with the storage identification number. This will help to ensure that sample traceability records accurately reflect storage location. This will also help to ensure that human and non-human samples are stored separately.
10.	T2(b)	The DI is advised to implement a formalised procedure for documenting disposal in NDM so that full traceability for all samples is maintained.
11.	PFE2(c)	The DI is advised to implement formal frequent alarm testing in NDM to assure themselves that the alarm system is functioning correctly and will alarm when temperatures deviate from their expected range.
12.	PFE3(c)	The DI is advised to review temperature records for trends. This may help to identify potential future freezer breakdown before it happens.
13.	PFE3(c)	Staff are provided with suitable PPE. The DI is advised to ensure that staff wear PPE appropriately/ The HTA observed several examples where staff did not wear full appropriate PPE when accessing samples in storage facilities.
14.	N/A	The DI is advised to ensure the HTA licence is on display in all areas where samples are being stored under the licence, which is a standard condition of the licence set out in Research Sector Annex B. *"A copy of the Certificate of Licence (first page of licence) describing the activity authorised by the licence must be displayed at the premises to which the licence relates in a position or positions in which it can be read easily by persons who are involved in the carrying out of licensed activity or providing relevant material for use for the purpose of activities governed by the Act, or who may wish to do so".*

Concluding comments

There are a number of areas of practice that require improvement, including 5 major shortfalls and 13 minor shortfalls.

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

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 11/07/2017

Report returned from DI: 09/08/2017

Final report issued: 29/08/2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 30 May 2018

Appendix 1: HTA standards

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

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

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

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

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

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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