Site visit inspection report on compliance with HTA minimum standards

University of Surrey

HTA licensing number 12365

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**

28 - 30 May 2013

Summary of inspection findings

The University of Surrey (the establishment) was found to have met several of the HTA standards. However, ten minor shortfalls were identified across a number of different HTA standards relating to consent, governance arrangements, storage and disposal.

The HTA found the Designated Individual (DI), the Corporate Licence Holder (CLH), the practices and premises to be suitable in accordance with the requirements of the legislation, subject to the identified shortfalls.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

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

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

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

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

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

Background to the establishment and description of inspection activities undertaken

The University of Surrey currently stores over 1000 samples of relevant material including tumour tissue, muscle biopsies, urine, blood and saliva samples. These samples have been obtained from living patients seen either during clinical consultation at another licensed establishment or healthy volunteers recruited for research studies through the university. Samples have also been obtained through collaboration with research centres in the European Economic Area (EEA) and the USA. Consent for use of relevant material for research purposes is usually obtained by the referring clinician or principal investigator for the research projects in question.

The DI is the Deputy Vice Chancellor (Research and Innovation) at the University. The CLHC is the Director of Health and Safety. The CLHC provides considerable support to the DI and PDs in relation to HTA requirements for activities conducted under the licence. There are four Persons Designated (PDs) within the Faculty of Health and Medical Sciences (FHMS): Senior Research Fellow (Biochemistry and Physiology Department); Consultant Oncologist/Senior Lecturer (Microbial and Cellular Sciences Department); Professor of Human Metabolism (Nutritional Sciences) and the Director of the Clinical Research Centre (CRC). Each PD has delegated responsibility for activities relating to relevant material stored within their respective areas of activity, although the Surrey CRC is currently not storing any relevant material on-site.

The establishment has been licensed by the HTA since September 2007 and this site visit, undertaken on 28 to 30 May 2013, was its first routine inspection. The visit included a visual inspection of the premises (sample receipt areas, processing laboratories and storage facilities – principally a number of freezers maintained at either -20ºC and -80ºC across the Stag Hill and Manor Park sites) and formal interviews with the Designated Individual, the Corporate Licence Holder Contact, the four PDs and other staff working under the licence.

A traceability audit was carried out on nine frozen samples in total, a minimum of two samples each from the respective four main research groups. Each audit trail included: review of evidence of receipt, consent documentation, storage and data entry onto the establishment's management information systems (which, depending on the department in question, were either electronic or paper-based records). All tissue samples were labelled and coded. No anomalies or discrepancies were found on the majority of selected examples during the traceability audits. However, information relating to one selected sample was not correctly recorded in the corresponding paper records although the sample in question was located within the correct freezer and was itself correctly labelled. An additional sample was chosen for this particular research group and all related information was correctly recorded.

A document review of the establishment's policies and operational procedures was also conducted. This included review of example consent forms, audit schedules, risk assessments, material transfer agreements (MTAs) and other contracts, respective quality manuals and the University draft policy for 'Human Tissue Governance'.

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

HTA standards not met:

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 code of practice	Although the establishment itself does not always seek consent, there is no Standard Operating Procedure (SOP) for obtaining consent in accordance with the Human Tissue Act 2004 (HT Act) and the HTA Code of Practice (CoP) on Consent (Code 1) for occasions when consent is obtained by university staff.	**Minor**
	Consent forms vary from one department to another. Most consent forms currently in use do not fully reflect the expectations as set out in the CoP on consent, particularly in relation to clearly stating options for either future use of material for other research projects, other scheduled purposes or disposal.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	The establishment does not yet have an over-arching governance framework in place. There is no evidence of formal, minuted governance meetings which focus on matters relating to licensable activities. The University draft policy for 'Human Tissue Governance' indicates the existence of a Human Tissue Governance Group embedded within current University governance structures, with clear reporting lines. This Group is not yet in place. The Quality Management System (QMS) is not fully developed and there is evidence of inconsistency in its implementation for licensable activities across the different research groups. For example: • SOPs cover some, but not all, activities under the licence; • The format of SOPs varies between different research groups. Lack of centralisation for a core set of procedures has led to some variability in practice in some instances and duplication of effort in others.	**Minor** **Minor**
GQ2 There is a documented system of quality management and audit	To date, some *ad hoc* audits have been carried out by some research groups but there is no systematic schedule of audits encompassing all areas of licensable activities.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The establishment should be able to satisfy itself that no relevant material is held on-site without appropriate consent provisions for storage of material beyond either the completion of a clinical trial study and/or defined period of REC approval. Currently, the establishment is unable to do this across all research groups.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	There are a number of Health and Safety risk assessments but there are no documented risk assessments for procedures associated with licensable activities. *Please refer to advice item 13*	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records	Temperature monitoring of critical storage areas is inconsistent. Some research groups monitor freezers on a continuous basis whilst others do not. There are sufficient contingency arrangements at the Manor Park campus. However, research groups at the Stag Hill campus currently have very limited contingency because the spare freezer on-site is faulty and unavailable for use.	**Minor**
PFE 5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	Although there is an alarm monitoring system for freezer units for most of the departments, this is not subject to routine testing except in one research group. As such, the majority of staff working under the licence are unaware as to whether the respective alarm systems are functional. Additionally, there are no formal out-of-hours arrangements in the event of freezer breakdown for one research group at the Manor Park campus and freezer temperatures are not remotely monitored for that group. As such, there is a potential risk to the integrity of stored samples in the event of freezer failure left unattended over an extended period of time. *Please also refer to advice item 13*	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue	To date, a limited number of samples have been disposed of. Based on available records, there was no indication that disposal of tissue has been undertaken in a manner inconsistent with HTA requirements. However, existing SOPs for disposal do not reference (or detail) either the HT Act or CoP on Disposal (Code 5) requirements. *Please also refer to advice item 19*	**Minor**

Advice

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

No.	Standard	Advice
1.	-	Operationally, matters relating to tissue governance are currently managed by the CLHC and respective PDs with respective postholders having a number of additional main responsibilities as senior members of academic or research staff. Although the DI discharges his own statutory duties appropriately through the CLHC and PDs, it is recommended that the establishment review current staffing structure and assess issues of demand and capacity in relation to specific activities under the licence. This is in order to assure itself that these activities can be effectively managed, moving forwards, by an appropriate member of staff with lead responsibility for the implementation of an effective quality system and other governance arrangements across the various research groups.
2.	C1	The DI is advised to consider amending all University consent forms so that they make reference to the Departmental Ethics Committee approval study code.
3.	C1	Imported material should be obtained, transported, stored, used and disposed in accordance with agreed consent provisions. The HTA considers it good practice to ensure that appropriate mechanisms are in place regardless of the source of material stored for the scheduled purpose of research. The DI is advised to review the practical guidance set out in the HTA CoP for Import and Export (Code 8).
4.	C2, GQ1, GQ5, D2	The DI is advised to review contractual details (within material transfer agreements and other equivalent agreeements) relating to consent provisions for human material supplied by external organisations. This is in order to more clearly define the supplier's responsibilities in relation to removal of relevant material to ensure that informed consent is in place. Additionally, it is advised that agreements should, where necessary, include details for the storage of any remaining relevant material beyond the completion of a research study and/or the defined period for REC approval

		and also specific instructions relating to disposal arrangements.
5.	C3	It is advised that periodic refresher training is provided to staff involved in seeking consent so that individuals maintain an awareness, and are kept abreast, of regulatory requirements relating to consent.
6.	GQ1	The DI is advised to review the information described within the Univeristy draft policy for 'Human Tissue Governance' to ensure that it is an accurate reflection of existing practices and procedures and the governance systems either planned or currently in place, prior to its formal ratification. Additionally, it is recommended that the establishment considers the creation of a Master File for human tissue governance issues which sets out the essential requirements of a robust QMS including standardised templates for a core set of SOPs (e.g. consent, disposal, adverse events, contingency arrangements), risk assessements, consent form templates and sample logs.
7.	GQ1	The establishment is advised to review respective quality manuals and relevant core SOPs so that there is improved consistency of formal procedure for activities relating to referenced HTA requirements. The DI is advised to consider implementing a system of signature logs to evidence the reading and understanding of SOPs by staff members across all research groups. Although existing arrangements are working effectively given the relatively limited scope of material currently held under this licence, this approach may help ensure staff are appropriately trained should activity levels continue to increase in the future.
8.	GQ2, GQ6	In developing a schedule of audits (at both the Stag Hill and Manor Park sites), the DI is advised to outline the frequency and range of audits to be conducted. Audit findings would need to be documented and respective research groups would need to have a system in place for ensuring that non-conformances are resolved in an appropriate time frame. The majority of relevant material sampled can be traced and is effectively supported by either paper records for the majority of research groups or a specific tissue tracking database for one research group. However, one sample relating to one research project could not be located within the designated location. Whilst this information was backed up elsewhere in laboratory notes, this suggests that there may, on occasion, be issues of accurate record keeping and storage. The establishment would benefit from regular audits of inventory or record content (covering areas such as the consent process, product receipt, storage, transportation, ethics approval end dates and disposal) across all research groups to check for completeness, legibility, accuracy and compliance against existing documented procedures.
9.	GQ4	Currently, the establishment maintains a number of local tissue registers. If the DI considers this a suitable model moving forwards (or a centralised register), it is advised that registers should provide information on when tissue samples stored under NHS REC approval are approaching their respective expiry dates or that consent obtained is either project-specific or enduring.
10.	GQ5	Currently, MTAs do not clearly define which samples are associated with particular MTAs. The DI is advised to integrate the review and oversight of MTAs into the proposed work of the Human Tissue Governance Group to enable more robust oversight of material (both imported and material

		transferred from within the UK to the university).
11.	GQ6	One research group identified that it stores existing holdings, collected before the implementation of the HT Act in September 2006. This frozen material is mainly stored in an archives area. The DI is advised to consider risk assessing the continued storage of existing holdings if there is no intended use of this material.
12.	GQ7	The DI is advised to implement a centralised system for the internal reporting of adverse events relating to licensed activities. This would potentially serve as a basis for identifying any trends and points of learning to be shared between research groups.
13.	GQ8	The establishment has a clear risk assessment (RA) process in place with a strong emphasis on COSHH assessments. The DI is advised to extend RAs to include potential risks related to tissue loss, loss of tissue integrity and loss of traceability, and the risk of receiving tissue with incomplete or non-conforming consent documentation and actions to be taken in such circumstances.
14.	PFE2	The DI is advised to routinely keep records of the cleaning and decontamination of respective storage units. Currently, there is variability across research groups in this regard.
15.	PFE3	Respective SOPs should clearly state locations of back-up freezers. Additionally, it is recommended that contingency freezers are routinely kept empty in the event that relevant material needs to be moved to these units in an emergency. The DI is advised to formally risk assess the current situation and determine whether contingency arrangements are sufficient for main freezers holding relevant material at the Stag Hill campus.
16.	PFE3	The FHMS Business Continuity Plan does not currently reference or provide details of the contingency storage arrangements either on-site or off-site in the event of an emergency. The DI is advised to review the plan and update accordingly.
17.	PFE3	The DI is advised to increase the frequency for temperature monitoring for -80ºC freezers. Routine daily recording of freezer temperatures will allow establishment staff to potentially identify trends prior to any freezer breakdown.
18.	PFE5	The DI is advised to consider making provision for on-going annual maintenance and routine servicing of critical equipment.
19.	D1	The DI is advised to consider how to ensure the consistent use of bagging of human tissue separately from other clinical waste so that relevant material is appropriately disposed of, in accordance with HTA regulatory requirements.
20.	D2	During a traceability audit, the time, reason and method of disposal was not recorded for a sample. The DI is advised to consistently record key disposal information in all instances.

Concluding comments

The establishment is committed to applying good practice and to sharing learning across the faculty in relation to HTA regulatory requirements. Some activities are managed well but there is not yet consistency of practices and compliance against the standards by all research groups for all activities. Some areas of strength were identified. For example, one group, in particular, has developed an effective tissue tracking database detailing movement and storage locations of samples (including a robust grid system for sample identification) and details of research use. In fact, all groups have local ID tracking systems with unique identification numbers generated at the level of individual samples. This facilitates a robust chain of custody process for the majority of samples stored for individual research projects. Another group routinely tests freezer alarms at three month intervals by simulating environmental conditions for alarm activation.

As highlighted above, there are a number of areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

The HTA requires that the DI addresses the ten identified shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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 ten shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 13 June 2013

Report returned from DI: 20 June 2013

Final report issued: 5 July 2013

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: 18 October 2013

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures in place are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place

- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

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

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

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

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

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.

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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.