Site visit inspection report on compliance with HTA minimum standards

The University of Sussex

HTA licensing number 12119

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**

31 October 2012

Summary of inspection findings

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 the University of Sussex (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to internal audit and risk assessments.

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

This report refers to the activities carried out by the University of Sussex. 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 Human Tissue Act 2004 and has been licensed by the HTA since 2007. This report describes the first routine site visit inspection of the establishment, which took place on 31 October 2012.

At the time of the inspection, relevant material was being stored under this licence by both the School of Psychology and the School of Life Sciences, with collections being held in the Pevensey Building, the John Maynard Smith Building and the Genome Damage and Stability Centre (GDSC). Samples held in these collections are sent to the establishment by collaborators or commercial organisations based in the UK or overseas, or they are collected on site from study participants for use in specified research projects. The GDSC also holds a collection of samples held primarily for diagnostic purposes. Surplus material from this collection is sometimes used for research purposes if appropriate consent is in place.

Many of the collections held under this licence have approval from a recognised research ethics committee (REC) or have been sourced from REC-approved tissue banks. As such they are exempt from the licensing requirements of the Act, subject to certain requirements. Where this was found to be the case, the establishment's systems relating to the storage and use of this material were not assessed as part of this inspection. Other collections were being held as part of specific research projects with university REC approval.

The inspection, which included a visit to each of the buildings listed above, included interviews with key members of staff working under the licence, including the Technical Services Manager, who is also the Designated Individual, the Chair of the Ethics Committee,

the Research Governance Officer and the NER Diagnostic Service Manager. A review of documentation relevant to each group's activities and a visual inspection of the premises was also conducted as part of the inspection.

An audit of eight samples held in storage and one sample distributed to a collaborator was performed during the inspection. Storage locations were cross-checked with records and files were reviewed to ensure that they contained all relevant documentation, including consent forms and transportation/delivery records. The samples chosen for the audit were representative of the range of relevant material stored under the licence and included examples of skin biopsies, saliva and buchal swabs, and samples of brain tissue. A variety of storage formats were also included in the audit, including storage in 4^{o}C fridges and -20^{o}C and -80^{o}C freezers, storage in liquid nitrogen, and storage at room temperature of samples embedded for electron microscopy. Minor transcription errors in records associated with several of the samples were noted, although these were resolved using supplementary documentation (see shortfall GQ2/4 below).

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit	Although evidence of audits was seen during the inspection, the establishment had not set out a clearly defined schedule of audits in relation to the licensable activities being conducted. Findings and corrective actions arising from completed audits were not documented in such a way that would ensure that any issues identified during audits would be resolved in an appropriate manner and timeframe. Completion of corrective actions was not consistently documented.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although the establishment has risk assessments in place for many of their experimental procedures, these focus primarily on the health and safety of those involved in the activity and do not currently address the risks associated with the licensable activities themselves. Completion of risk assessments addressing such issues would bring the establishment in line with the HTA's requirements, but also the establishment's own Code of Practice which states that activities relating to the acquisition, storage, use and disposal of human biological material require risk assessment.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to ensure that consent forms are completed accurately and that a consistent approach, such as the initialling of boxes, is used to evidence that consent has been given.
2.	GQ1	The DI is advised to review the frequency of the Human Tissue Governance Committee meetings to ensure that they continue to fulfil their intended purpose. At present, these meetings are scheduled annually. However, more frequent meetings would enable the establishment to review audit findings, incident reports and their closure, and SOPs on a more regular basis, helping to ensure timely resolution of any potential issues.
3.	GQ1 and GQ5	The DI is advised to review the establishment's SOPs to ensure that they contain no minor factual inaccuracies, such as links to incorrect SOPs, and that they accurately reflect the establishment's current approach to licensable activities such as the recording of consent and the system used to document sample receipt/distribution.
4.	GQ4	The DI is advised that all staff should adhere to a consistent, accepted procedure for correcting errors in written records. Although examples of good practice were seen during the course of the inspection, such as the striking through of errors with a single line and the initialling and dating of corrections, this approach was not employed by all of the groups working under the licence. SOPs relating to the management of records should be updated accordingly.
5.	GQ6	Although the establishment's records clearly state whether consent has been given for the use of samples in research, the DI is advised to review the way in which this is recorded in the establishment's biopsy database. In particular, the DI should consider whether the headings used in the current database provide sufficient clarity as to whether samples donated for diagnostic purposes have also been consented for research use.
6.	PFE1	Although the establishment has in place a number of safeguards relating to activities conducted in the liquid nitrogen storage facility, such as in-built oxygen

		alarms and a system of colleague notification prior to commencement of work in this area, the DI is advised to consider whether the implementation of a clear 'no lone working' policy and the use of personal oxygen alarms would help further reduce the risks associated with working in this facility.
7.	PFE3	The establishment was found to have implemented a number of robust systems to ensure that material stored under the licence is secure and readily identifiable. However, the DI is advised to review the establishment's approach to the temporary storage of samples outside of the principal storage areas to ensure that it adequately reduces the risk of accidental sample damage or loss. This could include, for example, the consistent use of clearly labelled secondary containers.

Concluding comments

The HTA saw several examples of good practice during the course of the inspection.

The establishment has implemented a clear Code of Practice on the use and storage of human tissue and has written a wide variety of SOPs covering licensable activities that apply to each of the research groups working under the licence. These are available through the University's website, which also contains a wide variety of information relating the Human Tissue Act, including links to training modules, consent and licensing flowcharts and key contacts.

The approach to local consent seeking was found to be robust. The systems employed by the establishment have received input from the University research ethics group, and the forms and documents used to evidence and support the consent process are detailed and clear. Consent training is also provided to undergraduate students, most notably those in the School of Psychology, where this is appropriate to the studies.

The establishment has put in place robust contingency arrangements in case of equipment or power failure in any of the storage areas. This includes spare storage capacity in each of the facilities and clear plans for sample relocation in the event power loss in any of the buildings or across the site in general. Back-up power sockets have also recently been mapped and labeled to ensure that critical equipment can be relocated if needed.

It was also apparent during the inspection that considerable effort had gone into cataloguing archival holdings. Samples dating back more than 40 years have been incorporated into the establishment's current databases and storage facilities, helping to ensure that there is good oversight of their ongoing storage and making them more readily accessible for future use should the need arise.

Two areas of practice were identified during the inspection that require improvement, resulting in minor shortfalls. These relate to the establishment's current approach to audit and the requirement for the establishment to conduct and document risk assessments for all licensable activities, such as the storage, use and distribution of relevant material, in addition to their existing Health and Safety risk assessments.

The HTA has given advice to the Designated Individual with respect to the establishment's approach to documenting consent and how consent information is captured on their databases. Advice and guidance has also been given with respect to some of the establishments SOPs with a view to removing minor factual inaccuracies and ensuring that

they reflect current working practices. The HTA has also suggested more regular governance meetings to help ensure continued compliance in the future.

The HTA requires that the Designated Individual addresses the 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 26 November 2012

Report returned from DI: 7 December 2012

Final report issued: 13 December 2012

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: 14 March 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.

   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.