Site Inspection Report for
Clinical Sciences Research Institute
Licence 12297

Licensed for the
Storage of relevant material which has come from a human body for a Scheduled Purpose

21 – 22 July 2010

Final Version

Introduction

1. The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes such as research, transplantation, and education and training. The requirements of the HTA are set out in the Human Tissue Act 2004 (HT Act) and the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. There are supplementary requirements for those establishments storing tissue for transplantation and they are summarised in HTA Directions 001/2006.

2. As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.

3. Under the HT Act, the HTA has a statutory responsibility to make judgements about the suitability of the Designated Individual, Licence Applicant (Holder), premises and practices in relation to the licensed activities. These responsibilities are set out in Schedule 3 to the HT Act, which is the framework for the HTA's approach to licensing and inspection.

4. The HTA must satisfy itself that the Designated Individual (DI) is a suitable person to supervise the activity to be authorised by the licence and that they will undertake the following duties:

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

5. The HTA must satisfy itself that the applicant for the licence is a suitable person/entity to be the holder of the licence.

6. The HTA must satisfy itself that the premises are suitable for the activity to be authorised by the licence.

7. To fulfil its statutory responsibilities, the HTA must be able to assess whether an establishment is suitable to carry out one or more of the activities regulated by the HTA. Suitability is assessed through a process of inspection. Inspections can be routine or risk based, announced or unannounced.

Inspection Process

8. HTA defines inspection as a process encompassing desk-based review, on-site assessment and analysis of relevant written, numerical, verbal and visual information to evaluate the establishment's compliance with expected standards. Desk-based reviews, described as phase one inspections, focus on the evaluation of the compliance report submitted by the Licence Applicant and Designated Individual, as well as any additional information provided by the establishment at the request of the HTA. On-site assessments, described as phase two inspections, focus on a review of the establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. Where the inspection process identifies that a standard is not being met, additional conditions may be placed on an establishment's licence to

ensure that appropriate action is taken to address the non-compliance/s.

9. Both desk-based review and on-site assessments may lead to advice and guidance for improving practice in one or more areas.

Judgements

10. To enable the HTA to make effective judgements about the suitability of the DI and the Licence Holder, the suitability of the premises and the suitability of the practices taking place on the premises under the supervision of the DI, the HTA standards were developed under four high-level headings:

    - Consent
    - Governance and Quality
    - Premises, Facilities and Equipment
    - Disposal

11. The evidence gathering during inspection focuses on these standards, with particular emphasis on any areas identified as requiring special attention in phase one of the inspection, as detailed above.

12. Throughout the inspection process, standards are assessed using the same four-point numerical scale used by the DI in the completion of the initial compliance report.

Numerical scale	Interpretation
1	Standard not met
2	Standard partially met
3	Standard almost met
4	Standard fully met or exceeded

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

The Inspection Report

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

15. Once the factual accuracy of the report has been agreed with the establishment, it will be published on the HTA website.

Inspection Report for the Clinical Sciences

16. The Clinical Sciences Research Institute (CSRI; the hub and its satellite, the Department of Biological Science (DBS), are part of the University of Warwick. CSRI is located in the recently built Clinical Sciences Building on the Walsgrave Hospital site. The DBS is situated in buildings on the Gibbet Hill Campus of Warwick University, which date back to the 1970s.

17. Both hub and satellite carry out the storage of relevant material for the scheduled purpose of research in connection with disorders, or the functioning, of the human body. At the time of the inspection staff reported that only 31 samples of nasal polyps were stored at the hub and two freezers containing unidentifiable material were at DBS. At the time the establishment had misinterpreted the licensing exemption provided by the HT Act to apply to all ethically approved research projects, including those where ethical approval was obtained from a research ethics committee (REC) not fulfilling the statutory requirements for a REC required by the licensing exemption. Since the inspection the DI has re-assessed the material held under the licence and has confirmed that imported human samples not held under NHS REC approval consist of serum and plasma only and are therefore not relevant material (see GQ2).

18. The two freezers containing unidentifiable material, which have been accumulated prior to 2001, appear to largely consist of whole blood, and potentially plasma, serum, urine and possibly small pieces of cardiovascular biopsies. They belong to a researcher who holds an honorary position with the University. The establishment reported that attempts to ascertain the amount and origin or type of material from the researcher over a period of several years have not been successful. Advice and guidance on this situation will be provided separately from the report.

19. The inspection team comprised:

    Christiane Niederlaender – HTA Regulation Manager, lead
    Kate Rolfvondenbaumen – HTA Regulation Manager, support

20. The timetable for the site visit was developed in consideration of the results of phase one of the inspection process. Attention was focused on the quality management system and general licence management.

21. The results of the audit trail of stored material are described in GQ6.

Compliance with standards, Codes of Practice and Directions

Consent

Standard	Assessment	Score
C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Code of Practice.	The standard is almost met. All consent forms are ethically approved, and where consent is obtained via University Hospitals Coventry and Warwick (UHCW), researchers can access consent forms via patient records. Where material is brought into the establishment from elsewhere, there is a process at DBS by	**3**

	which the origin and consent background of the material is ascertained. The same process is envisaged for CSRI and should be fully implemented there (refer to proposed condition 1). A memorandum of understanding is in place between UHCW and the University, which includes the consent process.	
C2 Information about the consent process is provided and in a variety of formats.	The standard is almost met. The memorandum of understanding with UHCW makes appropriate reference to consent requirements and the draft SOP on consent is well set out. At UHCW there is access to independent interpreters when required. As a number of processes are not fully implemented yet; the establishment should refer to proposed condition 1 for full compliance.	**3**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The standard is almost met. Staff taking consent are jointly appointed by the University and UHCW, the latter provide general and project specific consent training for doctors taking research consent. CSRI is also looking to implement an in house consent training module. It was unclear at the time of the inspection whether some researchers are involved in taking consent from healthy volunteers without having received training (advice and guidance 1).	**3**

Governance and Quality

Standard	**Assessment**	**Score**
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The standard is partially met. The establishment has a good governance system for the licence and regular meetings are held. Suitable staff have been tasked with the drafting and implementation of policies and SOPs and have produced a very good and proportionate set of procedures. However, the new systems now require full implementation. Condition 1 is proposed to address this deficiency.	**2**
GQ2 There is a documented system of quality management and audit.	The standard is partially met. A very good quality manual is in draft form, and so are the revised SOPs; these should be implemented. There are plans for a rolling schedule of audits	**2**

	and spot checks. However, the establishment need to first verify which material is stored under the licence. This is addressed by proposed condition 2. Note: The DI has submitted additional information indicating that it has now been ascertained which material is held under the licence. Imported material consists of serum and plasma, all other material is used in the course of NHS REC approved projects. A condition is therefore no longer required.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	The standard is almost met. There is an induction programme, staff appraisals and training and reference manuals. A draft HTA training programme will be implemented from September 2010 onwards (advice and guidance 2).	**3**
GQ4 There is a systematic and planned approach to the management of records.	The standard is almost met. There are good systems for records managements at CSRI. At DBS this was less evident due to the fact that all material, except the two freezers of unidentifiable material, were believed to be held under licensing exemptions. Condition 2 addresses this deficiency. The system from CSRI could easily be implemented at DBS if required. Note: The DI has submitted additional information indicating that a condition is no longer required (see GQ2).	**3**
GQ5 There are documented procedures for distribution of body parts, tissues or cells.	The standard is almost met. Material transfer agreements are in place whenever samples are acquired from elsewhere or distributed. Researchers are required to ascertain the consent background of the material before bringing it to the establishment. At DBS there is an 'import' procedure for samples where these details are checked by the PD. There is a draft SOP which reflects current practice but which is not yet implemented (refer to condition 1).	**3**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The standard is almost met. There are good traceability systems in place for all human material stored at CSRI. An audit trail of the nasal polyps was able to reconcile stored material with the available records. At DBS only two freezers were deemed to be under the licence and the content of these freezers cannot be inventoried as the responsible researcher is unavailable. The samples have	**3**

	been quarantined.	
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	The standard is fully met. Incidents are reported and reviewed. Appropriate corrective and preventative action is taken,	**4**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The standard is almost met. Risk assessments are undertaken on a project specific basis. The storage itself has not yet been risk assessed (advice and guidance 3).	**3**

Premises, Facilities and Equipment

Standard	**Assessment**	**Score**
PFE1 The premises are fit for purpose.	The standard is fully met. Risk assessments of the premises were reported to be in place but were not provided. Storage of Ultra Low Temperature (ULT) freezers is in dedicated rooms. Premises are access-controlled.	**4**
PFE2 Environmental controls are in place to avoid potential contamination.	The standard is fully met. Records of decontamination were kept and staff are provided with PPE. All laboratories are at minimum category 2.	**4**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	The standard is almost met. The ULT storage at CSRI is monitored and connected to a dial-out system. The room itself is air conditioned and temperature monitored also with dial-out alarm. At DBS ULT freezers are in a dedicated room with air conditioning but no remote monitoring. ULT are subject to twice daily visual monitoring during the week, but not at weekends (advice and guidance 4). The electricity grid at DBS is operating on borderline capacity and there have been power outages. Staff reported that backup generators were installed within 3 hours so that no serious damage occurred (advice and guidance 5).	**3**
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to its destination.	The standard is fully met. Material is transferred subject to Material Transfer Agreements. Transport conditions are developed according to the requirements of the material to be transported.	**4**
PFE5 Equipment is appropriate for use, maintained, quality assured,	The standard is almost met.	**3**

validated and where appropriate monitored.	All freezers holding human tissue at CSRI are under maintenance contracts. Some maintenance is also in place at DBS.	

Disposal

Standard	Assessment	Score
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	The standard is fully met. The establishment disposal policy and procedure complies with health and safety requirements. The establishment only disposes of material from the living but is aware of the disposal requirements for post mortem material.	**4**
D2 The reasons for disposal and the methods used are carefully documented.	The standard is almost met. The draft SOP for disposal and associated recording form is very good but requires implementation (refer to proposed condition 1). Currently use and disposal at CSRI are recorded on project specific spreadsheets, which exist for all human material including that stored under NHS REC approval. Clinical waste disposal forms also record the name of the disposing staff and the samples numbers, but do not link back to the individual projects. At DBS no such spreadsheet currently exists based on the assumption that all material, bar the two freezers, are stored under NHS REC approval. Therefore it is important that this assumption is verified (see proposed condition 2).	**3**

Conclusions

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

Suitability of DI and LH

23. The DI, Professor John Davey, has made significant efforts to improve compliance since taking up the role and he is suitable for the role. The licence holder is University of Warwick, with the named contact Mr Jon Baldwin, the Registrar. This arrangement is suitable.

Suitability of the Premises

24. The premises are suitable but the establishment should have regard to paragraph 29 and advice and guidance therein to ensure full compliance with all standards in future.

Suitability of Practices

25. The practices are suitable, but the establishment should comply with the requirements set out in paragraph 28 and 29 to ensure full compliance.

Summary comment

26. The HTA is satisfied that the establishment is suitable to be licensed for the storage of relevant material which has come from the human body for research in connection with disorders, or the functioning, of the human body..

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

27. No conditions were in place on the licence at the time of the inspection.

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

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

No	Regulatory reference	Conditions (including reasons for conditions)
1	GQ1	**Condition** By 1 March 2011, the Designated Individual (DI) shall ensure that all aspects of the draft quality manual, draft SOPs and planned training programmes are fully implemented. The DI shall inform the HTA's Regulation Directorate in writing when this condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'. **Reason** Since taking up the role in September 2009, the DI has overseen an overhaul of the current policies and procedures under the licence. These must now be fully implemented to ensure compliance with the HTA licensing standards.

Advice and guidance

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

No	Regulatory reference	Advice
1	C3	It is advisable that the DI ascertains which members of staff are involved in seeking consent, and whether they have all been suitably trained.
2	GQ3	The DI should consider integrating HTA training into the induction training for new staff.
3	GQ8	The DI is advised that the storage system itself should be risk assessed for damage or theft.

4	PFE3	The DI is advised to consider installing dial-out alarms for freezers, at DBS, storing human tissue or to develop more a detailed system for alarm checking by security staff over weekends and holiday periods.
5	PFE3	The DI is advised to document emergency procedures in case of future power outages.

Report sent to DI for factual accuracy: 13 August 2010

Report returned from DI: 26 August 2010

Final report issued: 21 September 2010, minor amendments 11 October 2010

TO: **University of Warwick, The Licence Holder (named contact Mr Jon Baldwin)**

AND TO: **Professor John Davey, The Designated Individual**

NOTICE OF PROPOSAL TO VARY LICENCE

(Paragraph 8 of Schedule 3 to the Human Tissue Act 2004)

TAKE NOTICE that on the 21 September 2010 the Human Tissue Authority ("the Authority") made a proposal to vary the licence issued by the Authority to the University of Warwick, licence number 12297, in respect of:

- The storage of relevant material which has come from a human body, for use for a Scheduled Purpose

It is proposed that the Licence be varied by the following conditions being added, namely:

Condition 1

By 1 March 2011, the Designated Individual (DI) shall ensure that all aspects of the draft quality manual, draft SOPs and planned training programmes are fully implemented.

The DI shall inform the HTA's Regulation Directorate in writing when this condition has been met, setting out details of compliance. This information should be sent to licensing.enquiries@hta.gov.uk or to the HTA offices marked 'Compliance'.

Reason

Since taking up the role in September 2009, the DI has overseen an overhaul of the current policies and procedures under the licence. These must now be fully implemented to ensure compliance with the HTA licensing standards.

The proposal to add the condition is made on the grounds that, under Schedule 3 paragraph 7(2)(b) of the Act the Authority is satisfied that the Designated Individual has failed to discharge his duty under section 18 (b) of the Act in that he has failed to secure that suitable practices are used in the course of carrying on the licensed activities.

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If you wish to make representations about the proposal you must give notice to the Authority within 28 days beginning with the date of this notice. Provided such notice is given by you within the period specified above, the Authority will, before making its determination, consider any representations that you wish to make which may be: -

(a) oral representations made by you, or a person acting on your behalf;

(b) written representations made by you.

If you do not give notice within the period specified above, the Authority will proceed to make its determination.

Dated 21 September 2010

Signed:___ _____

Dr. Chris Birkett
Head of Regulation
Human Tissue Authority