Site Inspection Report for
[name of establishment]

Licensed for the
[type of licence] and Other Scheduled Purposes

[date]

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 may be published on the HTA website.

Inspection Report for [name of establishment]

16. [Name of establishment] [outline here the activities of the establishment].

17. A phase two inspection of [name of the establishment] was carried out on [date inspection carried out].

18. The HTA inspector was accompanied by a Specialist Advisor. The role of the Specialist Advisor is to provide advice and guidance to the HTA inspector during a site visit. Specialist Advisors are aware of the confidential nature of their work and have signed a confidentiality agreement accepting that they are under an obligation not to use or disclose confidential information obtained during an on-site inspection visit.

19. The inspection team comprised: [insert names of team here]

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 [insert details here], reflecting the conditions of the licence granted to the establishment.

21. [*Either* insert details of audit trail *or* give a very brief description and state "The results of the audit can be found under HT Standard 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.		**1 2 3 4 N/A**
C2 Information about the consent process is provided and in a variety of formats.		**1 2 3 4 N/A**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.		**1 2 3 4 N/A**

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.		**1 2 3 4 N/A**

GQ2 There is a documented system of quality management and audit.		**1 2 3 4 N/A**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		**1 2 3 4 N/A**
GQ4 There is a systematic and planned approach to the management of records.		**1 2 3 4 N/A**
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		**1 2 3 4 N/A**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		**1 2 3 4 N/A**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		**1 2 3 4 N/A**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		**1 2 3 4 N/A**

Premises, Facilities and Equipment

Standard	**Assessment**	**Score**
PFE1 The premises are fit for purpose.		**1 2 3 4 N/A**
PFE2 Environmental controls are in place to avoid potential contamination.		**1 2 3 4 N/A**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.		**1 2 3 4 N/A**
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.		**1 2 3 4 N/A**

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		**1 2 3 4 N/A**

Disposal

Standard	**Assessment**	**Score**
D1 There is a clear and sensitive policy for disposing of human organs and tissue.		**1 2 3 4 N/A**
D2 The reasons for disposal and the methods used are carefully documented.		**1 2 3 4 N/A**

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. [insert detail here]

Suitability of the Premises

24. [insert detail here]

Suitability of Practices

25. [insert detail here]

Summary comment

26. [whether or not the HTA is satisfied or not that the establishment is suitable to be licensed for the purposes that it has set out]

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

27. These refer to conditions placed on the licence during the phase one inspection process.

No	**Regulatory reference**	**Conditions (including reasons for conditions)**	**Progress against condition**
		Condition	

		Reason	

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)
		Condition **Reason**

Advice and guidance

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

No	Regulatory reference	Advice

Report sent to SA for factual accuracy: [date]

Report sent to DI for factual accuracy: [date]

Report returned from DI: [date]

Final report issued: [date]