Site Inspection Report for
UK Biobank
HTA licensing number 12002

Licensed for the
storage of relevant material which has come from a human body
for use for Scheduled Purposes

21-22 October 2010

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 licence holder 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 UK Biobank

16. This report refers to the activities carried out by UK Biobank ('the establishment'). The establishment stores blood, saliva and urine samples from 500,000 donors aged between 40-69 years old for a 30-year epidemiological project. Samples were collected from volunteer donors at assessment centres throughout the UK. Sample collection has now ceased, although some follow up sampling from a group consisting of 20000 subjects is planned. The working sample archive is based at the establishment's hub in Stockport, and samples from there will be distributed to researchers with appropriate project ethical approval in the future, or will be analysed on their behalf by the establishment and data supplied to them. A back-up sample archive is maintained at the satellite site in Wythenshawe, Manchester. The release of samples and/or data to researchers is expected to commence from Summer 2011.

17. A phase two inspection of UK Biobank was carried out on 21-22 October 2010.

18. The inspection team comprised:

19. The timetable for the site visit was developed in consideration of the results of phase one of the inspection process.

20. As part of the inspection process, three traceability audits were carried out. The results of the audits can be found under HTA 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.	This standard is fully met. Sample collection for the Biobank has now ceased. Systems and arrangements for obtaining donor consent were appropriate. Donors gave their consent for sample donation and access to health information using electronic touch screens at the assessment centres where their samples were taken, and received print-outs of their consent form to sign and to keep. Donors may withdraw their consent for use of their samples and /or health information at any time during the study, and the procedure is explained clearly in donor information leaflets and on the establishment's website. Robust systems are in place to ensure samples stored at the establishment have been or will be destroyed should a donor request it.	**4**
C2 Information about the consent process is provided and in a variety of	This standard is fully met. Sample collection for the Biobank has now	**4**

formats.	ceased. Donor information was available in multilingual formats.	
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	This standard is fully met. Nurses were on hand at assessment centres to provide guidance to donors.	**4**

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.	This standard is fully met. The establishment has a strong ethics and governance framework covering critical areas including consent, donor confidentiality and research access to data and samples. Detailed standard operating procedures (SOPs), prepared in Q-Pulse, cover all aspects of the establishment's activities. Staff must sign off each relevant SOP when they have read and understood them.	**4**
GQ2 There is a documented system of quality management and audit.	This standard is fully met. The establishment's ISO 9001 certification ensures that a rigorous quality management system, with a regular schedule of internal and external process audits, is in place. In addition, the ISO2005:27001 information security and management accreditation supports the secure storage and use of data. Every sample retrieval represents an audit of records. Databases are in an ongoing process of integration, and rigorous testing will be built in to that process of integration to ensure software systems remain fit for their purpose.	**4**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	This standard is fully met. Staff receive formal induction and training in tasks relevant to their role, which is recorded in their training logs.	**4**
GQ4 There is a systematic and planned approach to the management of records.	This standard is fully met. There is restricted access to electronic databases. Records are backed up to tape each day, and the tapes stored off-site. Samples are linked to donors only by the nine-digit number assigned to them at the assessment centres. Access to donor identifiable information through this nine-digit number is restricted to senior establishment staff, who must sign confidentiality agreements as a	**4**

	condition of employment. Donor identifiable information will not be released to researchers requesting samples and/or data.	
GQ5 There are documented procedures for distribution of body parts, tissues or cells.	This standard is fully met. The establishment will not distribute body parts. Distribution of samples and/or data to researchers under material transfer agreements (MTAs) is expected to commence from Summer 2011. MTAs are being drafted in preparation for this. Proposals to access samples and / or data are scrutinised to ensure there is appropriate ethical approval and are consistent with the establishment's ethics and governance framework and with donor consent.	**4**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	This standard is fully met. Each sample has a machine-readable two-dimensional barcode, and is traceable in databases through its storage plate number and freezer location. Three traceability audits were carried out during the inspection. Three samples were retrieved from the working archive and traced back via the donor identification numbers to the donors' consent forms. The locations of two sample plates in the back-up archive were reconciled with computer records. For two donors who had withdrawn their consent, the database was interrogated to confirm their samples had been removed, and disposal logs were reviewed. There was full traceability in each of the three audits and no anomalies were found.	**4**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	This standard is fully met. All non-conformances, including those which occurred at assessment centres, are logged and investigated.	**4**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	This standard is fully met. Breaches of HTA licence conditions, vandalism/theft and major disruption of services are incorporated in the establishment's Risk Register. All aspects of the licensed activity have been risk assessed.	**4**

Premises, Facilities and Equipment

Standard	**Assessment**	**Score**
PFE1 The premises are fit for purpose.	This standard is fully met.	**4**

	The hub and satellite premises are fit for their purpose. There is secure access at each site, with CCTV and intruder-deterrent systems in place. Oxygen levels are monitored by staff carrying personal sensors. There is a back-up electrical power supply for the hub. Temperature sensors have an autodial facility to alert key staff should an unexpected event lead to warming beyond acceptable temperature limits.	
PFE2 Environmental controls are in place to avoid potential contamination.	This standard is fully met. Samples are stored in plastic tubes with no risk of breakage.	**4**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	This standard is fully met. The establishment does not store human bodies or body parts. Storage facilities are appropriate. Samples at the hub and the satellite are maintained, respectively, at -80 ^{o}C and -190 ^{o}C using liquid nitrogen cryorefrigerant systems. Records are backed up to tape each day, and the tapes stored off-site.	**4**
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.	This standard is fully met. The establishment does not store or transport human bodies or body parts. Samples to be stored at the satellite are transported there from the hub in validated transport boxes packed with dry ice by establishment staff. Packaging used in receipt of samples from assessment centres has been validated by the use of dataloggers. Distribution of samples or data to researchers is expected to commence from Summer 2011. Samples may either be distributed directly to the researchers, or to approved laboratories for processing on their behalf, in which case researchers will receive data from the processing laboratory, not the samples. Samples will be distributed by courier.	**4**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	This standard is fully met. All critical equipment, such as temperature sensors, robots and cryorefrigerant systems receive regular preventative maintenance and servicing.	**4**

Disposal

Standard	**Assessment**	**Score**

D1 There is a clear and sensitive policy for disposing of human organs and tissue.	This standard is fully met. The establishment does not store human organs. Samples will be disposed of only at a donor's request. Donors may request their samples to be disposed of at any time during the study, using a withdrawal form. Details of the withdrawal process were provided to the donor at the time of donation and are available from the establishment's website.	**4**
D2 The reasons for disposal and the methods used are carefully documented.	This standard is fully met. Checking of sample barcodes prior to disposal is carried out, which minimises any risk that samples are retained without consent from the donor. Disposal by incineration is carried out by an external company, and a disposal log is, checked, countersigned and maintained	**4**

Conclusions

21. 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

22. The DI, Dr Tim Peakman, is Executive Director of UK Biobank. The DI has an excellent overview of activities, and is well-placed within the organisation to effect changes as required. The DI is suitable. The Licence Holder is the corporate body, UK Biobank, and is suitable. The named contact for the Corporate Licence Holder is Joyce Neeson.

Suitability of the Premises

23. The premises are suitable to carry out the licensable activity of storage.

Suitability of Practices

24. The practices at the establishment are suitable to carry out the licensable activity of storage.

Summary comment

25. The HTA is satisfied that UK Biobank is suitable to be licensed for the storage of relevant material which has come from a human body for use for Scheduled Purposes.

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

26. No conditions were placed on the licence during the phase one process.

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

inspection process

27. No conditions are proposed on the licence following the phase two inspection.

Advice and guidance

28. No items of advice and guidance are given following the phase two inspection.

Report sent to DI for factual accuracy: 29 October 2010

Report returned from DI: 02 November 2010

Final report issued: 05 November 2010