Queen's University Belfast

Research and Enterprise

Standard Operating Procedure

Research Governance

Title:	**Internal Audit of Human Tissue Authority Licensed Premises, Facilities and Equipment**		
SOP Reference Number:	QUB-HTA-003	Date prepared:	24 October 2012
Version Number:	v 5.0	Revision Date:	10 April 2017
Effective Date:	28 February 2013	Review Date:	April 2019

	Name and Position	Signature	Date
Author:	Dr Paula Tighe Research Governance Manager	----------	----------
Reviewed by:	Human Tissue Steering Group	----------	----------
Approved by:	Professor James McElnay, Chair Human Tissue Steering Group	----------	----------

This is a controlled document.
When using this document please ensure that the version is the most up to date by checking the Research Governance website

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Version 1.0	20/06/2013	Update of location names	2.0
Version 2.0	07/01/2014	Inclusion of a PD from another area in the audit process and change of name for Centre for Vision and Vascular Science	3.0
Version 3.0	06/10/2014	Periodic review. Queen's Online replaced by Research Governance Website included on cover page.	4.0
Version 4.0	10/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the procedures for the internal audit of premises licenced by the Human Tissue Authority (HTA) at the Queen's University of Belfast. The audit process will ensure that the premises, facilities and related equipment are fit for purpose and comply with the licensing standards required by the HTA and by the University's procedures for Human Tissue.

2. Introduction

The Human Tissue Act 2004 (HT Act) came into force on the 1 September 2006 and provides a framework for regulation of activities involving the removal, storage, use and disposal of human tissue. The HTA licenses premises to undertake such activities and sets out standards that establishments are expected to meet to ensure compliance with the HT Act. The University will conduct internal audits of licenced premises, the associated equipment and local systems to ensure compliance with the HT Act is maintained and provide assurances that the expected standards are adhered to.

3. Scope

This SOP applies to all University premises licensed by the HTA. It applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students.

4. Responsibilities

4.1 Research Governance Team

The Research Governance Team will conduct the audit of HTA licenced premises, facilities and related equipment within the University. The Research Governance Team will be responsible for undertaking the audit process accordance with this SOP, reviewing compliance and providing an audit report to the Human Tissue Steering Group (HTSG). When issues of noncompliance are identified, the Research Governance Team, in collaboration with the PD for the area and Designated Individual (DI), will draft a plan detailing the corrective action to be taken and the timescale required for implementation.

4.1 Person Designated

The Research Governance Team will be accompanied by a Person Designated (PD) for the area. A PD from another area will also take part in the audit process to enhance shared learning. The PDs are responsible for undertaking the audit process, as described in this SOP, in conjunction with the Research Governance Team.

4.2 Designated Individual

The DI is responsible for ensuring compliance with the conditions of the HTA licence and that the premises are suitable for the purpose. The DI can participate in the audit process at his/her discretion.

4.3 Human Tissue Steering Group

The HTSG is responsible for reviewing the audit report prepared by the Research Governance Team, highlighting areas of good practice for shared learning and endorsing recommendations for improvement.

5. Procedure

5.1 Preparation for Audit

The Research Governance Team will liaise with the PD to determine the schedule for the audits, including date, time and venue and identify any additional personal in the area that may need to be present. A mutually convenient date will be arranged and the area to be audited will be advised and sent a copy of the audit template (Appendix 1). The individuals to be notified will depend on the area to be audited but may include Centre Managers, School Managers, Directors of Research or Head of Schools as appropriate.

5.2 Frequency

All HTA licenced premises will be audited every three years or more frequently if requested by the DI or PD.

5.3 Locations to be inspected

The following sites will be subject to inspection:

MBC/BCH Licence 12044
- Centre for Cancer Research and Cell Biology;
- Centre for Experimental Medicine
- School of Pharmacy;
- Northern Ireland Molecular Pathology Laboratory;
- David Keir Building.

RVH Licence 12059
- Centre for Public Health.

Anatomy Licence 12113
- Anatomy licenced area, Centre for Biomedical Sciences Education.

5.4 Audit Process

The audit process will be carried out in accordance with the audit template detailed in Appendix 1.

The audit process will determine the compliance of the premises with HTA standards by inspection of the following:
- Local documentation, procedures and risk assessments;
- Security and access control systems;
- Environmental controls and health and safety;
- Storage facilities (including monitoring and tracking systems);
- Transportation arrangements;
- Disposal arrangements;
- Equipment maintenance and training;
- Relevant data storage systems (hardcopy and electronic).

5.5 Audit Report and findings

The audit team will compile a report detailing their findings, within four weeks of completing the audit. A template for the audit report is attached as Appendix 2.

The audit report will include:

- A list of identified non-conformities with HTA standards (graded as critical, major and minor);
- An assessment of how well HTA standards and guidance has been met and highlight areas of good practice;
- Where appropriate, a list of corrective actions to be taken to ensure compliance and a time scale for implementation;
- In the event of serious findings, a date for re-audit.

The audit report will be distributed to the DI, Directors of Research or Head of Schools as appropriate.

5.6 Audit Outcome

Where corrective actions are identified these will be discussed with the DI and the Director of Research or Head of School as appropriate and a time-scale agreed within which actions must be addressed. The level of follow-up required will be based on the nature of the audit findings. A follow-up visit may be scheduled or written assurances sought that recommendations have been implemented.

In the event that corrective action(s) is/are not completed in time for the re-audit, the Licence holder's representative will be notified. He/She or their nominee may deem it necessary to suspend all HT Act related activates until all actions are addressed.

5.7 Audit close out

Once all recommendations have been addressed and assurances gained the DI, PD, Director of Research or Head of School will be written to.

An aggregated report of audit activity and findings will be brought to the attention of the HTSG for their consideration and action, if required.

6. References

Human Tissue Authority http://www.hta.gov.uk/ (last accessed April 2017)

Human Tissue Authority Code of Practice and Standards E Research
https://www.hta.gov.uk/hta-codes-practice-and-standards (last accessed April 2017)

7. Appendices

Appendix 1 Audit template for HTA licenced premises
Appendix 1 Audit report template for HTA licenced premises

Audit template for HTA licenced premises

HTA Licence No:	**Site to be audited:**
Designated Individual:	**Person Designated:**
Audit Personnel:	**Audit Date:**
Other personnel present during the audit:	

Local documentation	**Yes**	**No**	**N/A**	**Comments**
Are Local Standard Operating Procedures present for the HT Act related activities? *(seek copies)*				
Are risk assessments present for HT Act related activities?				
Are document control and review methods in place for SOPs and RAs?				
Security and access	**Yes**	**No**	**N/A**	**Comments**
In what areas are HT Act related activities carried out at the site?				
Is access to these areas or the site controlled and restricted?				
Are locks or similar on doors if necessary?				
Environmental controls	**Yes**	**No**	**N/A**	**Comments**
Are there procedures in place to ensure the health and safety of staff, students and visitors?				

Are there procedures in place for the cleaning and decontamination of areas and equipment?				
Is suitable personal protective equipment provided for staff and students?				
Storage	**Yes**	**No**	**N/A**	**Comments**
What locations are relevant material stored at? *(include building name, room numbers, freezer/fridge identification numbers, fixed sample storage areas)*				
Is the material stored in in a secure environment?				
Are the storage conditions suitable for purpose?				
Are temperature monitoring systems in place? *(note method and how frequently temperatures are recorded)*				
Are temperature warning systems in place? *(note what systems are in use and the individuals who are required to respond when an alarm is raised)*				
Are contingency plans in place in the event of storage unit failure?				
Are appropriate labelling systems in place?				
Transportation	**Yes**	**No**	**N/A**	**Comments**
Are records maintained of material transport and delivery?				
Is there a system in place for ensuring traceability of material during transport?				
Are service level agreements in place with third party transport companies?				

Disposal	**Yes**	**No**	**N/A**	**Comments**
Are there clear local procedures for disposal of material?				
Does the disposal method comply with health and safety requirements?				
Are local disposal records available which detail: • Date of disposal • Name of person undertaking the disposal • Unique sample ID number (or series) • Method of disposal • Reason for disposal				
Equipment	**Yes**	**No**	**N/A**	**Comments**
Are there maintenance records or service contracts for equipment?				
Is there evidence of equipment calibration or quality assurance mechanisms?				
Are instructions and training provided for use for equipment where appropriate?				
Data Storage	**Yes**	**No**	**N/A**	**Comments**
Is data collected held in a secure, restricted access location?				
Are electronic files/records stored on password protected computers?				
Are backup systems in place for the storage of electronic data?				

The above details recorded on _____ are correct and accurate to the best of my knowledge.

Signature of Auditor …… ***Print Name……***

Signature of Auditor …… ***Print Name……***

Audit report template for HTA licenced premises

HTA Licence No:	**Site to be audited:**
Designated Individual:	**Person Designated:**
Audit Personnel:	**Audit Date:**
Other personnel present during the audit:	

1. Introduction

The purpose of this audit was to establish if the premises licenced by the Human Tissue Authority (HTA) were compliant with the requirements of Human Tissue Act, 2004 (HT Act), the licensing standards stipulated by the HTA and Queen's University, Belfast Standard Operating Procedures for Human Tissue.

This report documents the findings and observations made during the audit of [*insert premises/site].* Shortfalls have been categorised according to HTA grading of seriousness and the actions required have been specified. Were there have been critical or major shortfalls the actions must be addressed within 4 weeks from the date of this report. For minor matters, these must be addressed within 3 months.

Grading audit shortfalls (as defined by the HTA)

Critical shortfall

- Where there is evidence that there is a significant risk to human safety and/or dignity or a breach of the HT Act or associated Directions or
- Where there is a combination of several major shortfalls, none of which is critical on its own, but which in combination could constitute a critical shortfall.

Major shortfall

A non-critical shortfall that:

- Poses a risk to human safety and/or dignity;
- Indicates a failure to satisfactorily carry out procedures;
- Indicates a breach of the HTA Code of Practices, the HT Act or other statutory guidelines;
- Has the potential to become a critical shortfall;
- Where the University's SOPs for human tissue have not been closely adhered to;
- Where there is a combination of several minor shortfalls, none of which is critical on its own, but which in combination could constitute a major shortfall.

Minor shortfall

A shortfall which indicates a departure from expected standards but cannot be categorised as a critical or major shortfall.

2. Findings

Shortfall findings and comments are summarised in the table below.

Local documentation	**Yes**	**No**	**N/A**	**Comments**
Are Local Standard Operating Procedures present for the HT Act related activities? *(seek copies)*				
Are risk assessments present for HT Act related activities?				
Are document control and review methods in place for SOPs and RAs?				
Security and access	**Yes**	**No**	**N/A**	**Comments**
In what areas are HT Act related activities carried out at the site?				
Is access to these areas or the				

site controlled and restricted?				
Are locks or similar on doors if necessary?				
Environmental controls	**Yes**	**No**	**N/A**	**Comments**
Are there procedures in place to ensure the health and safety of staff, students and visitors?				
Are there procedures in place for the cleaning and decontamination of areas and equipment?				
Is suitable personal protective equipment provided for staff and students?				
Storage	**Yes**	**No**	**N/A**	**Comments**
What locations are relevant material stored at? *(include building name, room numbers, freezer/fridge identification numbers, fixed sample storage areas)*				
Is the material stored in in a secure environment?				
Are the storage conditions suitable for purpose?				
Are temperature monitoring systems in place? *(note method and how frequently temperatures are recorded)*				
Are temperature warning systems in place? *(note what systems are in use and the individuals who are required to respond when an alarm is raised)*				
Are contingency plans in place in the event of storage unit failure?				
Are appropriate labelling systems in place?				
Transportation	**Yes**	**No**	**N/A**	**Comments**
Are records maintained of material transport and delivery?				
Is there a system in place for ensuring traceability of material during transport?				
Are service level agreements in place with third party transport companies?				
Disposal	**Yes**	**No**	**N/A**	**Comments**
Are there clear local procedures for disposal of material?				
Does the disposal method comply with health and safety requirements?				
Are local disposal records				

available which detail: • Date of disposal • Name of person for whom disposal was undertaken • Name of person undertaking the disposal • Unique sample ID number (or series) • Method of disposal • Reason for disposal				
Equipment	**Yes**	**No**	**N/A**	**Comments**
Are there maintenance records or service contracts for equipment?				
Is there evidence of equipment calibration or quality assurance mechanisms?				
Are instructions and training provided for use for equipment where appropriate?				
Data Storage	**Yes**	**No**	**N/A**	**Comments**
Is data collected held in a secure, restricted access location?				
Are electronic files/records stored on password protected computers?				
Are backup systems in place for the storage of electronic data?				

ADDITIONAL COMMENTS

3. Conclusion

As there were no critical, major or minor audit findings, a re-audit will not be required.

4. Signatures

Auditor 1:

Date:

5. Corrective Actions Completed

Yes ☐ **No** ☐ **Not required** ☐

Name: **Date:**