King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: Governance Arrangements for the Administration of the Human Tissue Act at King's College London

Purpose
The purpose of this SOP is to describe the arrangements put in place to ensure appropriate governance of the Human Tissue Act Licence held by King's College London.

Scope
The scope of this SOP is to describe the channels of communication and hierarchy of responsibilities in place at KCL to facilitate the administration of the HTA licence. It covers everyone using human tissue, those responsible for areas within which tissue is stored and the reporting lines and functions of the senior team with the responsibility for the governance of the licence. It describes the reporting mechanisms in place and the responsibilities of each tier of staff.

Document Detail	
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Approved By	KCL HTA Governance Group [06/03/2018]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 17/6/2010	1.0	2.0	3, 5, 6, 7	2.1, 3, 4.1, 9	Web-page screen shot update
2. 17/6/2010			4 5 6 7 8	2.1.1 4.1 4.2 6.2 10	New DI Remove transportation SOP Longer SOP review period AE/I (Human application) report to HTA Sample traceability audit
3. 29/5/13	2.0	3.0	3,5,6, 7,8, 4 5 7 9	 2.1.1 4.1 5 10	Updated web-page screenshot Updated HTAGG members New SOPs added Staff HTA training requirements Audit schedule updated
4. 8/6/15	3.0	4.0	3 6	2 9.2	Update Governance structure and group membership Remove reference to transport SOP
5. 6/11/2017	4.0	4.1	3 5 6	2 6.3 10	Update Governance structure and group membership Remove annual report requirement Update audit frequency
6.1/3/2018	4.1	4.2	3	2.1.1	Update membership

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

1.1 User

It is the responsibility of all staff to ensure that:

1.1.1 They adhere to the procedure outlined in this SOP.
1.1.2 They inform the appropriate Designated Individual or escalate to the Chair of the Governance Group of difficulties in complying with HTA licence standards.

2 Governance Structure

The governance structure below allows for clear lines of communication between those working with human tissue, those facilitating the storage of the tissue and those with the responsibility for campus compliance with the Human Tissue Act.

Governance Group		
Denmark Hill Campus DI's	Guy's Campus & Franklin-Wilkins Building DI's	St. Thomas' Campus DI
Persons Designated	Persons Designated	Persons Designated
Principal Investigators	Principal Investigators	Principal Investigators
Other personnel	Other personnel	Other personnel

2.1 Governance Group

A Governance Group has been established to ensure that the College is compliant with the requirements of the Human Tissue Act in that all activity relating to the storage, usage and disposal of human tissue is covered by the appropriate HTA licences.

The Group shall meet at six-monthly intervals or as the request of the Chairman. The terms of reference of the Group are available on the KCL HTA web pages.

2.1.1 Governance Group Membership

The membership of the Governance Group is as follows:

Faculty Operating Officer, Faculty of Life Sciences and Medicine (in the chair): Mr Keith Newton

Member of the Audit Committee: Professor Susan Brain

HTA Licence Designated Individuals:
Professor Stephen Devereux, Research – Haemato-oncology Tissue Bank
Mr William Edwards, Public Display - Gordon Museum
Professor Farzin Farzaneh, Human Application - Haematological Medicine,
Dr Cheryl Gillett, Research – Guy's Campus & FWB,
Dr Dusko Ilic, Human Application - Assisted Conception Unit
Ms Fiona Sutherland, Research – St Thomas' Campus
Dr Claire Troakes, Research - Institute of Psychiatry, Psychology and Neuroscience & Denmark Hill Campus

Mrs Barbara Webb, Anatomical Examination - Department of Anatomy and Human Science

Invited Members:
Mr Bernard Freeman (Deputy DI - Research, IOP & Denmark Hill)
Dr Rebecca Prue, Experimental Cancer Medicine
College Biological Safety Officer: Dr Chris Bradley
College Safety Officer: Mr Anthony Scott

Secretariat: Research Policy and Operations Department

2.1.2 Role of the Group Chair

It is the role of the Chair of the Governance Group to manage the conduct of the group and report on its activities to the Board of KCL.
The key duties of the Chair are available on the KCH/HTA web pages.

2.2 Campus Groups

The membership of the relevant Campus Group's will be as follows:

- Relevant Designated Individual (in the chair)
- Other Designated Individuals from the Campus
- Representative(s) from Persons Designated active on the Campus
- Representative from the Technical Staff

2.2.1 Responsibilities of the campus groups

The responsibilities of the campus groups are available on the KCL/HTA web pages these responsibilities include:

- Compliance with the Act
- Monitoring effectiveness of the governance arrangements in place
- Considering applications from PIs for new areas of work with human tissue
- Reviewing new standard operating procedures
- Producing regular reports for the Governance Group

3 Policy Development

Policies will be developed to enable a quality management system based upon the good practice guidelines issued by the HTA to be established. These policies will be stored on the KCL/HTA web pages for easy access. Policies exist which cover:

- Adverse events/ Incidents
- Complaints
- Consent
- Disposal of human material

4 Standard Operating Procedures

4.1 Core SOPs

Core SOPs will be produced by the DIs working in collaboration. Core SOPs will be submitted to the Governance Group for approval prior to being uploaded to the KCL/HTA web pages.

Core SOPs are currently available for:

- Adverse events/ Incidents
- Audit
- Consent
- Creation, retention & destruction of research documents
- Disposal of surplus and unusable human material
- Governance
- Production of SOPs

4.2 Local SOPs

All laboratories must have SOPs for HTA related activities. These must be updated when procedural changes occur and reviewed at no more than two-yearly intervals. New SOPs should be produced in response to new procedures or equipment use. These SOPs will not be placed on the KCL/HTA web pages as they will describe local procedures only and will not be generic to all campuses.

4.3 Local Responsibilities

The Person Designated should keep a register of SOPs produced for use by their group and be responsible for ensuring they are updated and reviewed.

4.4 Version Control

An SOP for the creation and version control of SOPs has been produced and is available for use on the KCL/HTA web pages. This gives detailed instructions about version control, numbering and updating and review deadlines.

5 Induction of new staff

At induction, all new staff who will be using human tissue in their work or will be responsible for an area where human tissue is used will be expected to review the pages on the KCL/HTA web site to familiarise themselves with the quality management system in place. New staff who will be taking consent from participants, collecting or processing human cells/tissue should attend HTA/Consent training. Staff will also be expected to review local SOPs so they may be compliant with local procedures.
Details are available on the KCL/HTA web pages for staff to see if the licence covers their area of work.

6 Reporting Mechanism

6.1 Complaints

All complaints will be dealt with in a fair, open and timely manner, as outlined in the KCL Complaints policy. All complaints will be escalated to the KCL HTA Governance Group.

6.2 Adverse Events/ Incidents

Notification of an AE/I should be made to the Campus DI at the earliest opportunity using the AE/I form. The cause, consequence and implication will be graded by the DI who also informs the KCL HTA Governance Group Chair and Head of Research Policy and Ethics. All AE/I occurring in the human application sector will be reported to the HTA. AE/I should be included in the DI's activity reports.

6.3 Activity reports

If requested by the Campus DI, PD's should be able to provide an annual or update report of HTA-associated activities within their area. These reports will be

held by the DI, and used to compile a summary document of HTA activities for presentation to the Governance Group and the Audit, Risk and Compliance Committee.

7 Applying to be named under the licence

New staff or PIs whose samples require to be brought under the licence should apply to the DI of their campus. The DI will inspect the area for suitability and expect the staff member to demonstrate an understanding of the quality management system prior to agreeing for that area to be included under the licence. The DI will be expected to inform the HTA via the Governance Group that a change to the licensed area has taken place.

8 Sample Traceability

All PIs and staff using human tissue should be able to demonstrate the audit trail of a sample, when requested. The DIs, as part of their quality management checks, will expect staff to be able to track a sample from the consent form to disposal.

9 Standard Forms

A number of HTA activity related forms are available for download on the web-pages.

9.1 Consent

A standard consent form has been produced for use when human tissue is being obtained for research purposes. Use of the form is explained in the associated consent SOP

9.2 Material Transfer Agreements

A standard Material Transfer Agreement has been produced and must be completed when a Research Ethics Committee has not specifically approved transport of material to another establishment.

9.3 Adverse Event/Incident

The AE/I report form should be used in accordance with the associated SOP to report any occurrence, which may have compromised HTA licensable activities

9.4 Investigator KCL HTA Licence Cover Application

The Investigator KCL HTA Licence Cover Application form should be used by investigators who wish to apply to the DI for extension of the existing HTA Campus licence to cover their premises and activities.

10 Audit

All laboratories covered by the KCL HTA Campus licences will participate in regular audit activities. DI's will arrange for Campus audits to be carried out at six month intervals. Either a DI from another Campus, or someone with similar audit knowledge who is not a member of King's College London will lead one audit per year.

Sample traceability should be a component of all audits. Laboratories may be asked to carry out other internal audits at the request of the DI or PD.

A record must be kept of audited activities. Areas of non-compliance should be highlighted in writing to the PD along with recommended remedial action and timeline for improvement.

DI's will report on audit activities at the KCL HTA Governance Group meetings.