Policy and Standard Operating Procedure for Complaints associated with University activities regulated by the Human Tissue Act 2004

Number: KCL HTA 3	Version: 3.0	Date: Nov 2019
Approved: KCL HTA Governance Group [20/11/2019]		

1 BACKGROUND

1.1 The Human Tissue Act (2004), (HT Act), Statutory Instrument 2005 No. 919 came fully into force on 1 September 2006. The HT Act replaces the Human Tissue Act (1961), Anatomy Act (1984) and the Human Organ Transplants Act (1989). The aim of the HT Act is to provide a legal framework for regulating the storage and use of human tissue from the living, and the removal, storage and use of tissue from the deceased.

1.2 KCL is committed to maintaining the highest standards of quality in clinical and basic research and undertakes to ensure that any complaints levied against KCL in relation to the HT Act are dealt with according to KCL policy.

2. PURPOSE

2.1 This SOP aims to provide KCL Designated Individuals (DI) and those working under their supervision with clear steps for handling complaints that are associated with activities conducted under their HTA licence.

3. KCL HTA SOPS

All KCL HTA template SOPs must be used in accordance with applicable KCL policies and where relevant, in conjunction with local NHS Trust and other establishment policies and SOPs. They are designed to be used as a template and may require local tailoring by the DI or person delegated to develop SOPs before local implementation.

4. DEFINITIONS

Designated Individual: The person who is authorised and supervises the activities under a licence issued by the HTA.

Complaint: A complaint is an expression of dissatisfaction e.g. relating to procedures, conduct requiring a response. A complaint becomes formal when it is put in writing.

Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity of the performance of a specific function.

5. SCOPE OF THE SOP

5.1. This SOP describes the procedure to be taken if a complaint is made about the conduct of activities under a KCL HTA licence or by staff to whom the licence applies. Complaints about the Statutory and legal framework in which the Human Tissue Authority (HTA) operates or matters that are the responsibility of other regulatory bodies, for example the Healthcare Commission are not covered by this SOP.

6. RESPONSIBLE PERSONNEL

6.1 *Designated Individual (DI).* The DI is responsible and *ultimately accountable* for activities conducted under their licence.

6.2 *Person(s) Designated (PD) and personnel working under the supervision of the DI and/or PD including:* Research manager, Researchers, fellows and students, Laboratory/facility manager, Quality assurance/management personnel, Technicians, Database personnel, Academic related and support staff

6.3 *Other staff involved in the Management of HT Act activities*: Licence Holder, Trust Research & Development personnel

7. PROCEDURE

7.1 The DI/PD will ensure that:

- Ways of reporting complaints/concerns are clear and understood by those under their direction.
- Complainants are kept informed about the progress of their complaint at regular intervals.
- Complainants are advised of any constraints in terms of the investigation in relation to the limitations of the HT Act.
- Complaints are handled in confidence and effectively.
- The outcome of any investigation into a complaint is communicated as quickly as possible.
- When a complainant wishes to remain anonymous, where possible this should be respected. Where anonymity cannot be adhered to, this should be explained to the complainant.

7.2. Receipt of Complaints

Verbal complaints

- Should be dealt with, as far as possible, by the DI/PD or person delegated to handle complaints.
- Verbal complaints should be documented according to local procedures.
- A record should be made of all complaints raised and actions taken.
- If further action is required or expected this must be clearly documented.
- Records of complaints should be forwarded to Licence Holder.

Written Complaints

- Complaints within the scope of KCL's HTA Governance arrangements, should be forwarded to the relevant DI and the Licence Holder.
- The lead person handling complaints should be identified and an acknowledgment of the complaint sent to the complainant.

- A follow-up written response should be sent if an investigation takes place.

7.3. Process

7.3.1 Time Limit

There is no time limit but complainants should be made aware that a more satisfactory investigation and outcome is likely to result if the complaint is reported as soon as possible after the event/incident has occurred.

7.3.2 Acknowledgement

Health Faculty staff must ensure that the Licence Holder and relevant DI are made aware of any complaints associated with HTA governance. An acknowledgement of the complaint must be sent to the complainant.

7.3.3 Investigation

Complaints received will be forwarded accordingly for prompt review, investigation and /or action. Where issues have not been fully resolved on initial receipt, an acknowledgement will be provided within three working days that provides an outline of the complaints process. Where a full response can be provided within three working days of receipt of the complaint no acknowledgement is necessary. Where appropriate, the DI/PD (or delegated person) will carry out the investigation. When the investigation is complete the DI/PD will explain the outcome to the complainant (and confirm their findings in writing). The total time to conduct the investigation and inform the complainant of the result should be no longer than four weeks. Should a complaint investigation require a more in-depth investigation and as a result the process is likely to exceed the four-week period the complainant will be informed in writing at the earliest opportunity.

7.3.4 Confidentiality

Complaints made will be managed with due regard for confidentiality and in accordance with the requirement of the Data Protection Act 2018, KCL Data Protection Policy and applicable legislation and guidelines.

7.3.5 Implementing preventative/corrective action

The DI is responsible for implementing preventative and corrective action for activities conducted under their licence and to monitor any action arising from the complaint. A copy of the implementation plan should be provided to the Licence Holder.

7.3.6 Legal Claims

The process detailed in this SOP will cease where the complaint explicitly indicates an intention to take legal action in respect of the complaint and the complainant will be so advised. The procedure for Employers Liability and Clinical Negligence will then apply to any such claims and appropriate referrals made.

7.3.7 Disciplinary Procedure

This SOP is concerned with resolving complaints. It is not designed to apportion blame amongst staff, although some complaints after investigation may identify information about serious matters, which may lead to a disciplinary investigation.

7.4 If a complaint is upheld

- The Licence holder will be given a summary of the complaint, outcome and proposed remedial action.
- An apology by letter, telephone or in person will take place.
- The respondent will be provided with a full explanation of what happened and why
- Convey what action has been taken to ensure that issues surrounding the complaint do not re-occur.

7.5 If a complaint is not upheld

- The complainant will be notified in writing (or where appropriate in person).

- The respondent will provide a full explanation of what happened and why and why the complaint was not upheld.
- Where applicable, convey what preventative action has been taken to ensure that issues surrounding the complaint do not re-occur.

7.6. Licence Holder involvement
It may be necessary to refer a complaint to another KCL governance group, Vice–Principal or the Principal. If the complaint involves a partner NHS Trust, appropriate lines of communication will be established with the Trust involved.

7.7. Monitoring and recording
Complaints will be recorded confidentially and a complaint ID assigned, where necessary. Complaints should be monitored in order to identify the types of issues occurring,

This information should be used to improve procedures and systems. The Licence Holder and relevant DI will make a summary report of all complaints received to the KCL HTA Governance Group. This information will also be forwarded to the KCL Audit, Risk and Compliance Committee.

8. REFERENCES
The Human Tissue Act 2004 (Statutory Instrument 2005 No. 919)
HTA Codes of Practice
Data Protection Act 2018
KCL Data Protection Policy