

SOP title:	Complaints procedure related to human tissue
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Amendment log

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Abbreviations:

SOP: Standard operating Procedure

HT Act: Human Tissue Act

HTA: Human Tissue Authority

HTL: Human Tissue License

CoP: Code of Practice

CI: Chief Investigator

QAM: Quality Assurance Manager/Coordinator

PIS: Participant Information Sheet

DI: Designated Individual

ID: Individual Designated

Purpose: The purpose of this SOP is to ensure all relevant material is collected or sourced in full compliance with the HT Act 2004 and local governance and ethics rules.

Scope: This SOP applies to all members of University staff (academic and support staff including visiting, affiliated and honorary staff) and students working under the University's HT license number (TBC). Complaints related to patient care reside with the NHS Trust (or other care organisation) and cannot therefore be investigated through this system.

Introduction:

The HT Act is the legal framework which regulates the removal, use, storage and disposal of human bodies, organs and tissues. The HTA is the body set out by the HT Act to regulate these activities through the licensing of organisations wishing to conduct activities requiring human tissue. One of the conditions set out for a HTL is that the establishment has a system for managing complaints (GQ1) ⁽¹⁾.

BU is open to receiving feedback both positive and negative for all matters related to research. The purpose of this SOP is to ensure that complaints are recorded, investigated, feedback given to the complainant and research systems improved (when appropriate). Complaints may come from a number of sources, including but not limited to ⁽²⁾:

- From a patient or donor: for example how they were treated during a trial or how their tissue samples were handled subsequently
- From a researcher wishing to bring an issue to the attention of the DI
- From a member of the public directly to a member of staff by telephone or email

This SOP sets out the process for handling complaints relating to activities conducted under the HT License number (TBC)

1. Procedure:

When addressing a complaint, members of staff should bear in mind the following standards which are essential in order to bring all complaints to a satisfactory conclusion for all parties:

- Complaints should be viewed as an opportunity to improve participant's experience in research and therefore should be handled fairly
- All staff must be aware of participants' right to comment on the way they are treated whilst participating in research
- Participants should be assured that lodging a complaint will not affect their rights nor the care they receive, and they should be reminded of their right to withdraw from the study at any time.
- All complaints should be taken seriously regardless of the nature of the complaint
- All responses to complaints must aim at satisfying the complainant, which means it must address the substance of the complaint.
- If an investigation is required, both the complainant and the research team must be treated impartially
- When processing a complaint, staff should attempt to understand the event that triggered the complaint, when this event occurred, who was involved and what the complainant's desired outcome is. This information should be documented.

The process for managing complaints is described below and summarised in Appendix 1.

Step 1: Ensure the complaint reaches the relevant person

If the complainant is an NHS patient participating in a trial, or a healthy volunteer (donor), complaints should be directed to the email address given in the PIS. If the complaint is deemed to be related to the handling of tissue samples, it should be forwarded to the QAM email: (TBC)

If the complainant is a member of staff, the complaint should be directed to the QAM copying the DI

When a complaint has been received by a member of staff from a member of the public via email, the complaint must be forwarded to the QAM copying the DI

All complaints, including verbal complaints, must be documented by adding to the complaint tracker. While it is accepted that not all information required by the tracker will be available, recipients are encouraged to enter as much information as possible.

Step 2: Acknowledge receipt

A message must be sent to the complainant within two working days of receipt of the complaint, by either the recipient of the complaint, or another appropriate person (QAM, DI). The message should confirm that the complaint has been received and is being investigated.

Step 3. Follow up actions

Upon receipt of the complaint, the QAM/DI will contact the study CI in order to discuss and appropriate response.

It is recognised that complaints may differ in their perceived severity. If an appropriate resolution can be found at this time (for example, an apology) then this should be offered, and this should be recorded in the complaints tracker. The CI should be informed of the outcome of the complaint who in turn should confirm that the solution is satisfactory for all parties.

If a resolution cannot be immediately offered, an investigation should be conducted. In this instance, the process outlined in SOP “reporting and managing adverse events and incidents related to human tissue” should be followed.

Step 4. Resolution

Once the investigation has been completed, the DI or QAM will contact both the study CI and the complainant to discuss the outcome of the investigation and any actions that need to be implemented. If the complaint has been successfully resolved at this stage, the actions and outcome should be entered into the complaints tracker. If the complainant remains unsatisfied, then the issue shall be discussed at the next human tissue governance meeting where amendments to the action plan or alternative solutions will be sought.

2. References

- (1) Human Tissue Authority code of practice and standards. Code E -
Research: <https://www.hta.gov.uk/hta-codes-practice-and-standards-0>
- (2) National Cancer Research Institute (NCRI)/Confederation of Cancer Biobanks:
Biobank Quality Standard, collecting, storing and providing human biological
material and data for research, version 1, 2014.

Appendix 1. Summary of the complaints process

