**UREC-SOP-008: Managing Participant Complaints (non Human Tissue Authority)**

If you are working under the Human Tissue Authority licence, please make sure that you are using the latest version of the **HTA SOP-011.** The current versions are available from Blackboard>Organisations>Working with Human Tissue.

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| Reviewed by | University Research and Knowledge Exchange Ethics Committee (UREC) |
| Approved by | Research and Knowledge Exchange Steering Committee (19 June 2024) |
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**1. Background**

Institutions carrying out research should have an independent point of contact for receiving participant complaints.

**2. Purpose**

*This SOP outlines the steps for managing participant complaints that are associated with research and KE.*

*It may be suitable to use this process for complaints about researchers and/or their research and KE project, study or activity from non participants but others working with the researchers (advice should be sought from the RKEO and Head of School prior to implementing this process in those instances where the complainant is not a participant or potential participant). The complainant can also hold a dual or multiple roles and be both a participant and a researcher/collaborator in the project, study or activity.*

*This SOP describes the procedure to be taken if a complaint is made about the conduct of research and KE.*

***3. Procedure***

*The University’s Code of Practice Governing the Ethical Conduct of Research outlines that:*

1. *Recruitment materials including the participant information medium should include the contact details of the of the Head of School (or Head of College) and should be provided to participants. Where the Head of School is directly involved in the research, the contact details of the Head of College should be listed for participants.*
2. *Complaints should not be handled by the research and KE team or supervisors of student researchers. The research team, or supervisors of student researchers, must report the complaint to the Head of School.*
3. The Head of School (or Head of College) must inform the Principal Investigator that a complaint has been made (but not the nature of the complaint nor the identity of the complainant, except to state that a participant compliant has been initiated). This allows the Principal Investigator to report the complaint, which must be treated as an ‘incident’, and report it to the relevant Research and Knowledge Exchange Ethics Committee (REC) via the **VRE adverse events** **function** found on the VRE application homepage.
4. Where the Head of School (or Head of College) receives a complaint from a participant about research and KE activities covered by the HTA licence, they must inform the Designated Individual or Persons Designate of such complaint to investigate (and refer to the **HTA-SOP-011 Managing Participant Complaints {HTA}**). All other non HTA related participant complaints will be handled and investigated directly by the Head of School (or Head of College).
5. The Head of School must keep complainants informed about the progress of their complaint at regular intervals.
6. The Head of School must ensure that complaints are handled in confidence and effectively.
7. The Head of School must ensure that the outcome of any investigation into a complaint is communicated as quickly as possible.
8. The Head of School must ensure that when a complainant wishes to remain anonymous, this should be respected. Where anonymity cannot be adhered to, this should be explained to the complainant in advance of revealing their identity to others who may need to be involved in managing the investigation.

*Verbal complaints*

Should be dealt with by the Head of School or a colleague they delegate these (without a conflict of interest). Verbal complaints should be documented and where ethical approval is in place, reported to the internal REC by the Principal Investigator.

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 the Head of College (or if the Head of College is overseeing the complaint process, then their line manager should receive the records).

*Written Complaints*

Complaints within the scope of University of Westminster’s ethics governance arrangements, received by another colleague should be forwarded to the relevant Head of School by the recipient of the complaint (in a confidential manner).

The Head of School (or their delegate without conflict of interest) handling complaints should acknowledge the complaint being received to the complainant.

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

**3.1 When?**

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.

Incidents themselves must be reported within 24 hours by the Principal Investigator in line with the Ethics Code via the VRE Adverse Events function if ethical approval is in place.

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 Head of School (or delegated person) will carry out the investigation. When the investigation is complete the Head of School 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.

**3.2 Who?**

Heads of School (or Head of College) for participant complaints, in receipt of a non participant complaint (or a participant with a dual or multiple role) then advice will be sought from the Head of RKEO and the Head of School.

**3.3 How?**

*Confidentiality*

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

*Implementing preventative/corrective action*  
The Head of School is responsible for implementing preventative and corrective action for and to monitor any action arising from the complaint. A copy of the implementation plan should be provided to the Head of RKEO.

*If a complaint is upheld*

The Head of RKEO 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.

*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.

**4. Other related procedures and documentation**

It may be necessary to refer a complaint to another University of Westminster governance group, Pro Vice Chancellor or the Vice Chancellor. If the complaint involves a collaborating external organisation, appropriate lines of communication will be established with the organisation involved through the Head of RKEO and Head of School (UoW).

*Monitoring and recording*

Complaints will be recorded confidentially. Complaints should be monitored in order to identify the types of issues occurring. This information should be used to improve procedures and systems. The Head of School will make a summary report of all complaints received to the Head of RKEO. This information will also be forwarded to the University Research and Knowledge Exchange Ethics Committee and Research and Knowledge Exchange Steering Committee. For HTA related complaints, the procedure in HTA-SOP-011 will be followed and a summary report will be provided to the HTA Governance and Oversight Committee.

All complaints will be logged on the ‘Complaints Log’ form shown at Appendix 1 by the Head of School or their delegate.

*Appeals*

Where a participant complaint is not upheld the complainant will have a right of appeal based on material irregularity, within 30 days of the receipt of outcome from those investigating. The Appeal should be directed to the Head of RKEO. The Head of RKEO will acknowledge receipt of the appeal, within ten working days. A preliminary review of materials related to the Complaint process will be take place within 30 days of receipt of the appeal by the Head of RKEO.

**5. References and further reading**

Code of Practice Governing the Ethical Conduct of Research: <https://www.westminster.ac.uk/research/research-governance>

**6. Appendices**

**Appendix 1 Complaint Recording Log**

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|  |  | **Date/Initials** |
| Research Study: |  |  |
| Principal/Chief Investigator: |  |  |
| Name and address of complainant: |  |  |
| Date concern/complaint raised: |  |  |
| Nature of complaint: |  |  |
| Decision as to whether ‘serious adverse event’ (SAE) or complaint (incident: adverse event): |  |  |

**If deemed a complaint:**

|  |  |  |
| --- | --- | --- |
| Process agreed with complainant: |  |  |
| Summary of investigation findings: |  |  |
| Remedial action (if required): |  |  |
| Outcome of complaints meetings: |  |  |
| Store this log and any information and materials relating to the complaint investigation within the HTA Steering Group private SharePoint folder; ‘Managing Participant Complaints’ |  |  |

**Signed (Head of School or delegate, or Head of RKEO):**

**Date:**