Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Complaints from Research Participants**		
SOP Reference Number:	QUB-RGEI-019	Version Number:	FINAL v 1.0
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	Name and Position	**Signature**	**Date**
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

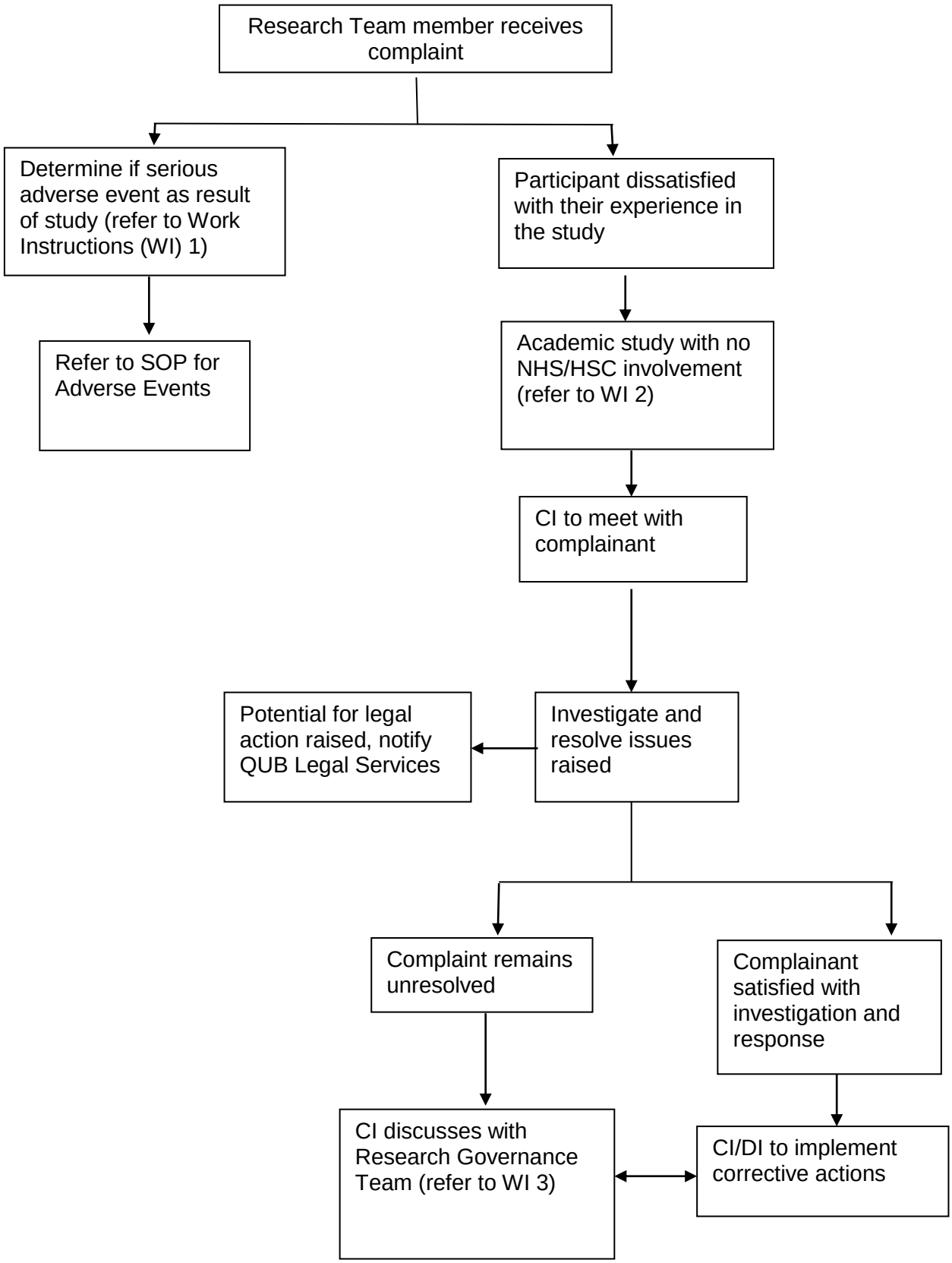
This Standard Operating Procedure (SOP) provides guidance to researchers as to how to manage complaints/concerns made by the participants in a research study. A core ethical principle is that every researcher must respect each individual research participant. All participants entering into a research project/clinical study must give their informed consent before they can become involved and this must be ongoing throughout the life of the study. Part of informed consent is the provision of information sheets to research participants. The Health Research Authority (HRA) guidance on information sheets and consent forms, states that participants should be given information as to how complaints will be handled, what compensation may available in the event of harm and who the first point of contact should be. These principles apply across all research within the University, including those reviewed by Faculty Research Ethics Committee.

2. Scope

This procedure applies to all research conducted involving human subjects conducted by University Researchers or those working on behalf of the University.

In the event of a complaint arising from the clinical care of a NHS/HSC service user the NHS/HSC complaints process should be followed.

3. Procedure


Research Team member receives complaint
Determine if serious adverse event as result of study (refer to Work Instructions (WI) 1)
Refer to SOP for Adverse Events
Participant dissatisfied with their experience in the study
Academic study with no NHS/HSC involvement (refer to WI 2)
CI to meet with complainant
Investigate and resolve issues raised
Potential for legal action raised, notify QUB Legal Services
Complaint remains unresolved
Complainant satisfied with investigation and response
CI discusses with Research Governance Team (refer to WI 3)
CI/DI to implement corrective actions

4. References

HRA guidance on information sheets and consent forms (last accessed January 2022). http://www.hra-decisiontools.org.uk/consent/

Human Tissue Authority (last accessed January 2022) http://www.hta.gov.uk/

Queen's University Belfast, Standard Operating Procedure, Informed Consent SOP-RGEI-006. http-://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Policies-procedures-and-guidelines/ (last accessed January 2022)

5. Appendices

Work Instruction 1 – Receipt and consideration of complaint
Work Instructions 2 – Addressing complaint
Work Instructions 3 – Closure/Escalation of complaint

Appendix 1: Formal Complaint Form

Work Instructions 1 – Receipt and consideration of complaint

1. Any member of the research team can receive a complaint, it is important each know the actions to take.
2. On receipt of a complaint or concern, the member of the research team must record the detail.
3. Using the information received and the researcher's knowledge of the study, the research team must assess the complaint/concern to:
    - Determine whether it is related to a serious event in relation to the study procedure (Serious Adverse Event (SAE)); or
    - How the participant has been treated whilst taking part in the study.
4. In the event of an SAE the SOP for Adverse Events (QUB-RGEI-006) should be followed.

Work Instructions 2 – Addressing Complaint

1. Once deemed a complaint, the matter must be dealt with as specified in the information sheet.
2. In the event the complaint has arisen because of clinical or social care matters, the NHS/HSC complaints process should be adhered to.
3. Where the complaint relates to research practice, the CI must discuss the complaint with the research participant and agree an appropriate approach. This should include:
    - How the complaint will be dealt with;
    - An approximate timeline for dealing with the complaint, which ideally should be no longer than 20 working days;
    - Who will be involved investigating the complaint;
    - Any immediate action required to remedy the issue raised;
    - That the complaint will be handled in confidence.
4. Where legal action is explicitly mentioned by the complainant or it is CI's view that a legal opinion could be necessary, the complaint must be brought to the attention of the University's legal services team.
5. Undertake a robust investigation. In the event that the complaint will require longer than 20 working days to complete the complainant must be informed of the delay.
6. Where matters of Research Integrity are identified they should be raised with the employing organisation's lead for research integrity.
7. Once the complaint has been investigated the CI, or a suitable designated individual, must meet with the participant and discuss the findings and any proposed remedial action.

Work Instructions 3 – Closure/Escalation of Complaint

1. Corrective actions identified following the complaint should be implemented. In a research study this is by the CI, where the matter relates to human tissue the Designated Individual (DI) should lead on corrective actions, in conjunction with the CI.
2. The complainant can determine whether they are satisfied with the outcome of the investigation and the proposed remedial action, if appropriate.
3. If the complainant remains dissatisfied the CI should report the formal complaint to Head of Research Governance, Ethics and Integrity (HRGEI) or their nominee, using the form attached as Appendix 1. For research studies regulated by the HT Act the CI must also inform the Designated Individual of any unresolved complaints.
4. The HRGEI, or nominee, in conjunction with the Director of Research and Enterprise will determine if further formal investigation is required. The HRGEI or nominee will inform the complainant in writing of the decision and advise the complainant of the timescale required to carry out any formal investigation, if deemed necessary.
5. Once completed, the HRGEI or nominee will inform the complainant of the outcome in writing.

Raising a concern or complaint

		Date & initial
Research Study:		
Chief Investigator:		
Complainant: name and contact details		
Date concern/complaint raised:		
Nature of complaint:		
Decision as to whether SAE or complaint:		
If deemed a complaint:		
Process agreed with complainant:		
Summary of investigation findings:		
Remedial Action (if required):		
Outcome of complaints meeting:		

Further actions (if required)		

Signed _____ (Chief Investigator, or local PI).

Date _____

Copy to: Site master file
Research Governance, Ethics and Integrity Team: researchgovernance@qub.ac.uk
Designated Individual (for Human Tissue Act 2004 regulated research studies only)