Standard Operating Procedure (SOP)

Handling Research Participant Complaints

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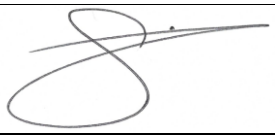
Author:	Georgia Bullock	**Title:**	Research Development and Governance Manager
Approved by:	Subhir Bedi	**Date:**	11/01/2022
Signature of Authoriser			

This is a controlled document.
The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version.
They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	New SOP	Lucy H H Parker
V2.0	New logo and Trust name and change of title from HRG to HRG	Deborah McCartney
V3.0	Update from HRG to HRGD. Addition of SGUL Director of Legal Services. Clarification of processes after a complaint is made	Subhir Bedi
V4.0	Reflecting changes in JREO to JRES and job titles and minor changes to delegations of responsibilities. Also, insertion of Associated JRES documents table.	Ali Alshukry/Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0027 Informed Consent JRESGOVSOP0006 Reporting of Adverse Events for CTIMPs	JRESWPD0023 General Research Definitions		

Contents

1. Background

Participant involvement in healthcare research must be on an entirely voluntary basis, and the procedures described in the Informed Consent SOP (JRESGOVSOP0027) must be followed. Part of the informed consent process should be an explanation of how to make a complaint if a participant is unhappy with any aspect of their involvement in the study.

The UK Policy Framework for Health and Social Care Research states that research teams are responsible for: "*ensuring participants' safety and well-being in relation to their participation in the research*" and that effective action is taken in the event of any errors or breaches.

Complaints

A contact number should be given. This may be the researcher, who can try to resolve the problem in the first instance. However, a participant may not wish to complain to the researcher if he/she is the reason for the complaint and may wish to make a more formal complaint.

When managing any complaint from a research participant, researchers must be aware of the complaints procedure of the organisation where the research is taking place.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP describes the process for managing complaints from participants taking part in a research study.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

The Chief Investigator (CI) is responsible for the overall conduct of the study, and the Principal Investigator (PI) is responsible for the conduct of the study at a particular site, and although certain responsibilities may be delegated to a research team member, the CI and/or PI have a duty to ensure that all research activities are carried out in compliance with the terms of ethical approval and Sponsor SOPs. The PI at the site is therefore responsible for handling participant complaints in the first instance.

The CI may seek guidance and advice from the Head of Research Governance and Delivery (HRGD) of the JRES. The CI must also liaise with the HRGD if the complainant wishes to escalate the claim or seek compensation.

6. Procedure

6.1 Participant Information Sheet (PIS)

When developing a PIS, clear instructions must be included that detail how and to whom a complaint can be made. This information should include the name and contact details for the person delegated by the Chief Investigator (CI) to be responsible for this action (if the responsibility has been delegated). This information should be discussed with the potential participant during the informed consent process so that they know how to complain should they need to.

Contact details should be provided for any group at the research site who have a role in managing complaints for the organisation, for example, NHS Trusts will usually have a Patient Advisory and Liaison Service (PALS) who can be contacted if a patient has concerns about their care. This offers the participant an alternative route of complaint if they do not feel confident in discussing their concern with the research team (or, for example, they wish to complain about the study team).

Should these options not be satisfactory, participants should be informed that they can contact the CI if they are unhappy with their research care.

6.2 Study Team Procedure

Where the research team is the first point of contact, they should record and assess the complaint against their research practice and decide if the complaint is related to how the participant has been treated whilst taking part in the study or whether the complaint relates to an incident in relation to the study procedure, for example a Serious Adverse Event (SAE).

If the latter is the case, the SOP for Reporting of Adverse Events for CTIMPs Sponsored by St George's (JRESGOVSOP0006) should be followed. If the complaint relates to a patient's general medical care, it should be referred to the Patient Advice Liaison Service (PALS) or equivalent service at the organisation responsible for their care.

If the complaint is research practice related, the extent of the complaint should be discussed with the participant and the CI informed of the situation.

A management approach should be agreed with the participant and recorded in their medical notes or research records. This approach must state:

- How the complaint will be dealt with
- An approximate timeline
- Who will be involved in reviewing the complaint
- Any immediate action that can be taken to correct the situation

Once the complaint has been reviewed and the findings approved by the CI, the CI or a designated person should discuss with the participant any findings and corrective actions that may result from the investigation.

The participant can now decide if they are satisfied that their complaint has been addressed and no further action needs to be taken, or whether further investigation is required.

If further investigation is necessary, the CI should discuss the complaint with the HRGD of the JRES who will review the case and the actions taken by the research team. If the HRGD feels that further investigation is required, the complaint will be assessed by the Research Governance Committee (RGC) and recommendations for corrective action made.

Should the participant remain unhappy with the review they will have recourse to follow St George's complaints procedures. https://www.stgeorges.nhs.uk/contact-and-find-us/compliments-and-complaints/

6.3 Compensation Claims

Where a participant requests compensation for an incident related to a St George's sponsored research study, the CI must inform the HRGD immediately and provide a written summary of the incident and an assessment of how it relates to the research study.

The CI must also obtain the participant's claim in writing, to be provided to the HRGD with their own assessment. Where a claim directly relates to a blinded drug or procedure, it will be necessary to unblind the participant before the claim can be progressed as insurers will be unable to assess the claim without this information.

For SGHFT sponsored research, the request will be referred by the JRES to the Trust's legal department for review against the NHS Litigation Authority (NHSLA) criteria for negligent harm cover.

If SGUL is the Sponsor, the request for compensation will be forwarded to the insurance company, copying in the JRES Director and SGUL Director of Legal Services.

Where a claim is not substantiated, the participant will be informed in writing by the appropriate person(s) within St George's.

7. References

http://www.hra-decisiontools.org.uk/consent/

8. Appendices

None associated with this SOP.