St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure

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Signature of Authorisor			

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They may print off this document for training and reference purposes.

Standard Operating Procedure (SOP)
Handling of Research Participant Complaints

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

1. Background

Participant involvement in healthcare research must be included on an entirely voluntary basis, and those procedures described in the Informed Consent SOP (JREOSOP0027) should 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 (v3.3 07/11/17)states that research teams are responsible for: "ensuring participants' safety and well-being in relation to their participation in the research" and that " and that effective action in the event of errors and breaches is taken.

Complaints

A contact number should be given. This may be the researcher, who can try to solve the problem in the first instance. However, a participant may not wish to complain to the researcher if he/she is the object of 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 procedures of the organisation where the research is taking place.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

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

3. Scope

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

4. Definitions

Not applicable to this SOP

5. Responsibilities

The Chief Investigator (CI) is responsible for the overall conduct of the study and although certain responsibilities may be delegated to a research team member, the CI has a duty to ensure that all research activities are carried out in compliance with the terms of ethical approval and Sponsor SOPs. The CI 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 JREO. The CI must also liaise with the HRG should the participant wish to escalate the claim or seek compensation.

6. Procedure

6.1 Patient Information Sheet Information

When developing a Participant Information Sheet, 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 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) whom 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).

Participants should be informed that they can contact the JREO of St George's if they are unhappy with their research care and do not wish to pursue other complaint routes.

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 (JREOSOP0006) 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 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 meet with the participant to discuss 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 Head of Research Governance (HRG) of the JREO who will review the case and actions taken by the research team. If the HRG 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 a research incident related to a St George's sponsored research, 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 JREO HRG 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 St George's University Hospitals NHS Foundation Trust sponsored research, the request will be referred by the JREO to the Trust legal department for review against the NHS Litigation Authority (NHSLA) criteria for negligent harm cover. .

If St George's, University of London is the Sponsor, the request for compensation will be forwarded to the insurance company, copying in the JREO 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 SGUL. ,.

7. References

JREO Informed Consent SOP (JREOSOP0027)

JREO Reporting of adverse events for CTIMPs SOP (JREOSOP0006)

http://hra-decisiontools.org.uk/consent/index.html

8. Appendices

Not applicable to this SOP