Managing Research Participant Complaints

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Author: Nihaad Abbass, Clinical Trials Monitor

Approved by: Gary Roper

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1. **PURPOSE**

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

2. **INTRODUCTION**

Participant involvement in healthcare research must be on an entirely voluntary basis, and those procedures described in the Informed Consent for Research SOP (SOP/JRCO/016) 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 National Research Ethics Service (NRES) guidance on information sheets and consent forms, version 3.5 May 2009, states:

**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 it is essential to take into account the complaints procedures of the organisation where the research is taking place.

3. **PROCEDURE**

3.1 **Information Provision**

When developing a Participant Information Sheet, clear instructions should be included that detail how and to whom a complaint can be made. This information should include the name and contact details of the person delegated by the Chief Investigator to be responsible for this action. This information should be discussed with the potential participant during the informed consent process.

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 Information 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.

Participants should be informed that they can contact the Joint Research Compliance Office at Imperial College if they are unhappy with their research care and do not wish to pursue other complaint routes.
3.2 Responsibilities
The Chief Investigator (CI) is responsible for the overall conduct of the study. 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 operational procedures.

3.3 Process
Where the research team is the first point of contact, they should record and assess the complaint against their research practice. They can decide whether the complaint is related to how the participant has been treated whilst taking part in the study or whether the complaint relates to a serious event in relation to the study procedure, for example a Serious Adverse Event (SAE). If the latter is the case, the SOP for Recording, Managing and Reporting Adverse Events in the UK (JRCO/SOP/001) should be followed. If the complaint relates to a patient’s general medical care it should be referred to the PALS or the 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 research records; which outlines:

- 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 Research Governance Manager (RGM) who will review the case and actions taken by the research team. If the RGM feels that further investigation is required the complaint will be assessed by the JRCO and recommendations for corrective action made.

Should the participant remain unhappy with the review, they will have recourse to follow College complaints procedures.

3.4 Insurance Claims
Where a participant requests compensation for a research incident related to AHSC sponsored research, the CI must inform the JRCO Research Governance Manager immediately and provide a written summary of the incident and an assessment of how it related to the research study.

The CI must also obtain the participants claim in writing to be provided to the JRCO with their assessment.

For Trust sponsored research, the request will be referred by the JRCO to the Trust legal department for review against the NHS Litigation Authority (NHSLA) criteria for negligent harm cover and the JRCO will liaise directly with the research participant to progress the claim.

Where the College is sponsor the CI will report the incident and claim as above. The JRCO will forward the claim request to the College Insurance Manager who will liaise with the insurer to progress the claim. The JRCO or Insurance Manager will liaise with the participant as appropriate.

Where a claim is not substantiated the participant will be informed in writing by the JRCO, and will be reminded they are still free to take legal action if unhappy with the outcome of the claim review.

Where a claim directly relates to a blinded drug or blinded 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.

4. REFERENCES


Joint Research Office Informed Consent for Research SOP (SOP/JRCO/016)

Joint Research Office SOP for Recording, Managing and Reporting Adverse Events in the UK (JRCO/SOP/001)