Managing Research Participant Complaints

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Version 2.0	15 Jul 2008	CRO name change
Version 3.0	08 Feb 2010	Annual review and RGIT name change
Version 4.0	14 Jul 2011	Annual review
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Version 7.0	25 Oct 2015	Scheduled review
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1. PURPOSE

This standard operating procedure (SOP) describes the process for managing complaints from participants taking part in research studies.

2. INTRODUCTION

Participant involvement in healthcare research must be on an entirely voluntary basis and the procedures described in the Informed Consent for Research SOP (RGIT_SOP_016) should be followed.

The informed consent process should include an explanation of how to make a complaint if a participant is unhappy with any aspect of their involvement in a study. The HRA website provides guidance on consent and participation information sheet (PIS) preparation.

Complaints – Contact details of where a complaint can be made should be given to potential participants.

- First point of contact might be your contact details or that of someone else within the research team.
- You should also provide contact details for someone who is independent of the research team for more formal complaints.

An example of possible wording that could be used is as follows:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details e.g. NHS Complaints Procedure or private institutional arrangements]. Details can be obtained from [insert details].

When managing complaints 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 (CI) 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. Details of the sponsor's indemnity policy (NHS or College) should also be included on the information sheet.

Participants should be informed that they can contact the Research Governance and Integrity Team (RGIT) at Imperial College if they are unhappy with their research care and do not wish to pursue other complaint routes.

3.2. Responsibilities

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

A management approach should be agreed with the participant and recorded in the 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 then 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 the actions taken by the research team. If the RGM feels that further investigation is required, the complaint will be assessed by the RGIT and recommendations for corrective action will be 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 Imperial College London or Imperial College Healthcare NHS Trust sponsored research, the CI must inform the RGIT 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 RGIT with their assessment.

For Trust sponsored research, the request will be referred by the RGIT to the Trust legal department for review against the NHS resolution criteria for negligent harm cover and the RGIT 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 directed above. The RGIT will forward the claim request to the College Insurance Manager who will liaise with the insurer to progress the claim. The RGIT 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 RGIT or Insurance Manager 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

The Medical Research Council (MRC) and Health Research Authority's (HRAs) online tool that gives guidance on consent and the preparation of information for participants.

SOP for Recording, Managing and Reporting Adverse Events in the UK (RGIT_SOP_001)

Informed Consent for Research SOP (RGIT_SOP_016)