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Managing Research Participant Complaints

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Version	Date	Reason for Change
1.0	21st March 2014	Review of SOP due
2.0	2nd March 2016	Reference to NRES removed and changed to HRA. Link to website provided

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for dealing with complaints from research participants taking part in research studies sponsored by Brighton and Sussex University Hospitals NHS Trust (BSUH).

2.0 Introduction

All participation in research studies must be on a voluntary basis and based on the information contained within the Patient Information Sheet .
Every Patient Information Sheet must contain details of the complaint process in accordance with the guidance from the HRA website: http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html

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]

A complaint does not need to be made in writing to be dealt with under this SOP.

3.0 Responsibilities

Chief Investigator
The Chief Investigator (CI) has the responsibility for designing the Participant Information Sheet containing full details of how to make a complaint.

Principal Investigator
The Principle Investigator (PI) or delegated person(s) taking consent has the responsibility of making the potential participant aware of this information as part of the informed consent process.

The PI and other members of the research team have the responsibility of dealing with complaints seriously and in an appropriate and timely manner.

Head of Research & Development (R&D)
The Head of R&D has the responsibility of dealing with all complaints that cannot be resolved by the PI/CI for the study.

It is the responsibility of the Head of R&D to keep a database of all complaints that are referred to him/her.

4.0 Procedure

Wherever possible a complaint should be dealt with immediately in an effort to resolve the problem as quickly and informally as possible. The nature of the complaint and the actions taken to resolve the complaint should be fully documented in the patient's notes.

If it is not possible to resolve the complaint informally then a full report of the nature of the complaint to include date, details of complaint, parties involved, witnesses if appropriate and any corrective action taken must be written and the PI must be given this report, if not already involved in the receipt of the complaint as well as the CI.

The PI must send a letter to the complainant within three working days of receiving the complaint acknowledging the complaint and outlining the process and timescales for resolution of the problem. This letter must contain details of how the complaint will be escalated if the complainant is not satisfied with the outcome, together with

contact details of the local PALS (Patient Advice and Liaison Service) office. A copy of the letter must be kept in the patient's notes.

The PI must carry out any investigation necessary to resolve the complaint and meet with the compl inant at the end of this process within 25 working days of receiving the original complaint. If it is not possible to conduct the investigation within this time frame the PI must inform the complainant as soon as possible with the reasons for the delay and advise them of the amended timescales.

If the complainant is still not satisfied then the complaint must be escalated to the Head of R&D. The PI must inform the Head of R&D within one working day of being advised by the complainant that they are not satisfied with the outcome of their original complaint.

The Head of R&D will acknowledge the complaint within two working days, advising the complainant of the investigation to be undertaken to resolve the complaint and inviting the complainant to a meeting to discuss this within 25 working days. A copy of the letter must be kept in the patient's notes.

The Head of R&D will confirm the outcome of the meeting to the complainant within 3 working days of the meeting. This letter must contain details of BSUH formal complaints procedure. A copy of the letter must be kept in the patient's notes.

If the complaint is still not resolved after meeting with the Head of R&D then the BSUH formal complaints procedure must be followed.

5.0 Training

This is a 'read and understand' SOP. Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross Referenced SOPs

N/A

7.0 References

NRES, Information Sheets & Consent Forms. Guidance for Researchers and Reviewers. Version 3.6,.1 March 2011