SOP Number 009

SOP Title **Managing Complaints Arising from Clinical Research**

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1. PURPOSE

The purpose of this SOP is to describe the standard procedures to be followed for handling complaints arising from clinical research when conducted by the University of Oxford.

2. INTRODUCTION

The Health Research Authority gives guidance on the content of information provided to participants, and this includes the requirement for an outline of how complaints can be made. The information should contain the contact name of the Investigator/Research Team who should attempt to resolve the complaint in the first instance. However, a participant may not wish to complain to the Investigator team if the latter are the object of the complaint, and may wish to make a more formal complaint. Details as to how to do this, such as Sponsor contact details, should also be included in the written information given to participants.
It is essential that any complaints arising are routed through the correct channels.

3. SCOPE

The scope of this procedure is for all clinical research studies sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Participant Complaint

Any report of dissatisfaction or general enquiry which expresses concern with the way in which a participant has been treated, or about the conduct of a study, made either by the participant or on their behalf, and which requires a response.

Serious Complaint

A complaint that has not been satisfactorily resolved by the study team and therefore requires Sponsor involvement and, through them, the Sponsor Insurance Officer. For example, this should always include instances where the subject matter concerns: harm to participants (other than where it can be readily demonstrated that the harm complained of was an expected progression of the disease, unconnected with the trial); any breach of confidentiality; initial complainant dissatisfaction following first response or any other matter where the possibility of legal action is intimated.

Serious Breach

A Serious Breach is a breach which is likely to affect to a significant degree (a) the safety, physical or mental integrity of the subjects of the trial or, (b) the scientific value of the trial.

5. RESPONSIBILITIES

Study Team

Review and resolve the complaint, if appropriate as outlined in section 6. Communicate details to the Principal Investigator at site, if appropriate. Maintain correspondence, chronological log if applicable and other documentation. Assess significance to procedure and/or systems.

Chief Investigator (CI)

Assess the seriousness of the complaint, and resolve the complaint, if possible. If resolution is not possible, or initial attempts at resolution do not appear to promise success, communicate details to the Sponsor. Provide support, maintain correspondence and other documentation. Assess significance to procedure and/or systems.

Sponsor Representative or delegated individual

Coordinate, investigate and plan the management of the complaint with communication to the Sponsor Risk and Insurance Manager (Research), if appropriate. Generate and maintain a chronological log or equivalent. Review and assess the submitted complaint and its significance to procedure and/or systems.

Risk and Insurance Manager (Research) (RIM)

Provide specialist advice, based upon the Sponsor's clinical trials and related liability insurance, as requested. Review and assess submitted complaint, and notify insurer/broker if appropriate.

6. SPECIFIC PROCEDURE

6.1 Initial Receipt of Information

Participant complaints may arise from a variety of sources, including participants themselves, relatives, participant representative (e.g. solicitor, advocate), Study Teams, or the Patient Advisory Liaison Service (PALS).

The initial recipient of a complaint should record and assess the complaint, generate a chronological log or equivalent and communicate to the CI without delay. The CI should assess the seriousness of the complaint, if not serious, acknowledge receipt as soon as possible, indicating when the complainant can expect further communication and make every effort to resolve the issue after preliminary investigation.

Any communication with the complainant should have oversight at a senior level.

If the complaint is defined as or becomes Serious (see section 4), the Sponsor should be notified immediately. Details and outcomes should be made available to relevant staff on a need-to-know basis.

- Any serious complaint must not be acknowledged without specific guidance from the Sponsor.
- All staff must be reminded of the need for confidentiality in communication and record keeping.
- Caution must be exercised when using any form of written communication (including text messages and emails) to the complainant.

Details of the complaint must be recorded and retained, with due respect to confidentiality, and with details of sender, addressee, date and time.

Any participant identifiers must be removed prior to complaint communication being forwarded from site.

6.2 Assessment and Management of Serious Complaints

In the event that the complaint is assessed as serious, regardless of resolution status, or if in any doubt as to how to resolve, the CI or delegate should inform the Sponsor immediately, who will then inform the Risk and Insurance Manager (Research) (RIM).
A plan for the management of the complaint will be formulated, including target response times. The RIM and another representative of the Sponsor will be involved;

- at each stage of the complaint management process
- ensure timely actions and responses,
- will review; discuss with the CI and the insurer (where appropriate);
- and agree written communication with the complainant.

All communication updates must be recorded and filed as in 6.1 above. The RIM and/or the representative of the Sponsor must be involved in all communication with the CI or delegate.

6.3 Potential Serious Breach

In the event that a complaint highlights a potential serious breach, the University's Core SOP 'Serious Breach of Good Clinical Practice' should be followed.

7. RELATED DOCUMENTS

University of Oxford Core SOP 008 – Serious Breach of Good Clinical Practice

HRA website: http://www.hra-decisiontools.org.uk/consent/content-sheet-support.html
PALS website: http://www.nhs.uk/chq/Pages/1082.aspx?CategoryID=68&SubCategoryID=153
MHRA website: http://www.mhra.gov.uk/#page=DynamicListMedicines

8. REFERENCES

UK Policy Framework for Health and Social Care 2017
Information Sheets & Consent Forms. Guidance for Researchers and Reviewers. National Research Ethics Service, March 2011

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.0	01 Jan 2014	First version of SOP	n/a
2.0	02 July 2015	Minor rewording to clarify and remove ambiguity.	1.0
3.0	21 Jan 2016	Additional detail added to responsibilities and procedure to emphasise the need for confidentiality and record keeping.	2.0
4.0	See page 1	Update to SOP in line with template, changes to Authoriser and Insurance Managers job title, update Related Documents and References	3.0