



COMPLAINTS FROM RESEARCH SUBJECTS ABOUT UCL SPONSORED STUDIES AND TRIALS

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Approved by the UCL Research Governance Committee
And endorsed by SLMS Research Board

Version history

		Main changes
Version 4	July 2014	Substantively revised
Version 5	July 2017	Updated to include situation where the Head of Department is the Chief or Principal Investigator, in this case the complaint needs to be overseen by the relevant Dean

COMPLAINTS FROM RESEARCH SUBJECTS ABOUT UCL SPONSORED STUDIES AND TRIALS

1. SUMMARY

This policy sets out the process by which complaints from research subjects in studies or trials sponsored by UCL and approved by the Health Research Authority should be managed. It describes:

- the oversight arrangements for complaints management,
- the procedures to be followed by staff who are involved in investigating, resolving and responding to complaints
- the procedures to be following when institutions other than UCL are involved in complaints
- the mechanisms for documentation of complaints

2. INTRODUCTION

The Research Governance Framework for Health and Social Care (Department of Health 2005, Second Edition), states that a key feature of a quality research culture is that:

Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research

and that

This involves learning from errors and complaints.

3. OBJECTIVES

The aim of the procedure is to ensure that:

- All complaints are dealt with by the most appropriate body eg UCL or NHS body - para 8.2
- All complaints are handled in a systematic and sympathetic manner
- All complaints are investigated thoroughly, fairly and quickly through liaison with the complainant, using a method of resolution agreed with the complainant
- The investigation is proportionate to the issue(s) being raised, is line with complainant desired outcome and is most relevant to the complaint.

The purpose of the complaints process should be to resolve the sources of the complainant's dissatisfaction and where necessary, to improve the quality of the service. UCL wants to make every effort to resolve the complaint including providing an appeals process.

4. SCOPE

This policy applies to all studies sponsored by UCL. It applies to all staff within UCL including those employed within SLMS Institutes and Divisions as well as those employed in Clinical Trials Units (CTUs) and research centres.

5. DUTIES

5.1 Executive responsibility for all complaints lies with the Vice Provost (Health), delegated to Deans, Directors of Divisions or Institutes and Faculty Managers. The Joint Research Office will support the process by co-ordinating and recording complaints.

5.2 The Director of Research Support will oversee the School of Life and Medical Sciences procedure for handling complaints from research subjects and their representatives. The Head of Risk and Regulation in the Joint Research Office will provide advice to patients and staff, registers complaints and monitor their progress through the investigation process.

5.3 Directors of Divisions or Institutes are responsible for investigations of complaints within their area. If the Director of Division or Institute is the Chief Investigator of the study which is subject of the complaint then the Dean of the relevant faculty will be responsible for overseeing the complaint. Whilst parts of the investigation may be delegated to an appropriate person, accountability for the timeliness and quality of the investigation and response to the complaint cannot be delegated. Directors or relevant Dean should seek statements from all relevant staff involved in the events leading up to the complaint and ensure that those statements are all received within the agreed timescale for the complaint response.

5.4 All Chief or Principal Investigators or relevant CTU study contacts (where the study is managed by an UCL affiliated CTU) are responsible for

- Ensuring participant Information sheets contain information about how to make a complaint. The suggested wording is

If you have comments or complaints about your participation in this research study/trial, please contact your study doctor. If you are not satisfied with the response, please contact the chief investigator [name ..contact details]

- Ensuring complaints are forwarded to the Joint Research Office [research-incidents@ucl.ac.uk](mailto:research-<u>incidents@ucl.ac.uk</u>) within three working days of their receipt
- Ensuring that the research team and/or CTU staff co-operate fully on any investigation

5.5 If the complainant wishes to discuss the complaint independently of the Investigator, they can contact London Independent Health Complaints Advocacy Service – POhWER - pohwer@pohwer.net , www.pohwer.net, 0300 456 2370 or for research subjects where the study has taken place the outside London, the local NHS Trust Patient Advocacy and Liaison Service (PALS).

5.6 UCL expects all complaints to be dealt with in a timely and efficient manner.

6.0 POLICY

Making a complaint

6.1 UCL must send to the complainant an acknowledgement of the complaint within seven working days and a final response within three months from the date on which the complaint was received. If it appears likely that it will not be possible for the UCL to send the response within three months, the complainant should be notified in writing and given an explanation.

6.2 Complainants must make the complaint to UCL usually not later than 12 months after the date on which the subject matter for the complaint occurred.

6.3 A complaint may be made may be made in person, by telephone, in writing or by email by:

- a research subject, or relative
- a person who is likely affected or likely to be affected by the action, omission or decision of UCL or staff employed by UCL.

6.4 If the complainant is not the research subject and the complaint may be related to disclosure of sensitive personal information on the research subject then consent from the research subject to disclosure must be obtained before any investigation can commence. If the research subject is deceased, information should only be disclosed to the next of kin.

Unreasonable Behaviour by complainants

6.5 Where the complainant exhibits unreasonable behaviour then the complainant should be warned that their behaviour could be classified as unreasonable and, should it continue, UCL may decline any further contact.

Unreasonable behaviour might include

- Harassment or aggression towards staff
- Frequently changing substance of the complaint
- Placing unreasonable demands on staff through request for excessive contact with staff
- Recording meetings or telephone conversations without prior consent
- Destruction or tampering with UCL records

7.0 LESSONS LEARNT FROM COMPLAINTS

7.1 All complaints and actions taken as a result of a complaint will be reviewed by the UCL Clinical Research Governance Committee. An annual report on the operation of this procedure, summarising the numbers of complaints considered thereunder and actions taken as a result, will be submitted by the Clinical Research Governance Committee to the UCL Research Governance Committee. In addition, where the Clinical Research Governance Committee deems a complaint considered under this procedure to raise particularly serious issues demanding the attention of the UCL Research Governance Committee, it may draw the matter to the attention of the latter Committee immediately.

7.2 Trends in complaints will be analysed by the Joint Research Office to inform UCL Chief Investigators and CTUs of wider implications.

8.0 PROCEDURE

8.1 Notification of a complaint

8.1.1 Letters or emails of complaint written to any staff about a UCL sponsored study must be forwarded to the Joint Research Office research-incidents@ucl.ac.uk within three working days of receipt.

8.1.2 The Joint Research Office will acknowledge the complaint in writing to the complainant within 7 working days and copy in the Director of the relevant Division, Institute or CTU.

8.1.3 The Joint Research Office must forward the complaint to the Director of Division, Institute or CTU within one day of receipt.

8.1.4 The Director of the Division or Institute or Dean where the complaint relates to a study undertaken by an institute Director, should write to the complainant to confirm the outcome of the investigation, normally within three months of receipt of the complaint. A longer timeframe may be agreed with the complainant or their representatives but the complainant must receive a response in writing within 6 months.

8.2 Complaints involving other institutions

8.2.1 Where the complainant is an **NHS patient** enrolled in UCL sponsored studies, there may be a difficulty in distinguishing between complaints that are related to care of the patient and complaints that concern the conduct of a study. In such cases, the Joint Research Office may contact the relevant NHS Complaints Manager at the site where the patient was enrolled or treated and if appropriate, forward a copy of the complaint.

8.2.2 The Joint Research Office will liaise with the NHS Trust complaints department to agree a lead organisation to act as the point of contact for the complainant, co-ordinate the investigation and response.

8.3 Contacting the complainant

8.3.1 Within seven working days of receiving the complaint, the Director of the Division, Institute or CTU, or a member of staff nominated by them, must contact the complainant or their representative by telephone, email or letter to advise the complainant on the process for handling the complaint and the timeframe.

8.3.2 The conversation with the complainant should enable the investigator to

- Define the investigation by understanding the events from the complainant's perspective and the gap between what happened and what should have happened
- Provide an opportunity to clarify what the complainant would like to see happen and to manage any unrealistic expectations
- Assist in obtaining any information or documentation needed

- Agree (as described in diagram 1) whether the complainant
 - Considers complaint resolved
 - Would like a written response
 - Would like a meeting

Any actions agreed must be reasonable and in proportion to the issues being complained of.

8.3.3 If telephone or other contact is not possible and messages are not returned, the Director should investigate the complaint and proceed towards a written response within three months. In exceptional circumstances, an extension may be agreed with the complainant.

8.4 Investigation

8.4.1. The Director of the Division or Institute or Dean is responsible for overseeing the management of complaints within his or her division. Records of the investigation should be kept including any statements, emails, letters and conversations with the complainant, causes of delay and actions taken.

8.4.2 Where appropriate, any investigation should be undertaken in conjunction with the appropriate manager of the Trial, the Chief or Principal Investigator, and/or the Head of the relevant Clinical Trials or Research Unit. In any event, the Chief Investigator will be kept fully informed of the remit and progress of any investigations and will be given a chance to comment on any letter sent to the complainant.

8.4.3 If another institution is involved, but UCL is the lead institution, the Director of the Division or Institute or Dean will review what information should be shared with the other institution.

8.4.4 On completion of the investigation, a written summary of the investigation and any action taken should be prepared. This should be forwarded to the Head of Risk and Regulation, Joint Research Office and the Vice Provost (Health).

8.5 Communication of findings and actions to complainant

8.5.1 The Director of the Division or Institute is responsible for communicating the outcomes of any investigations and any actions, to the complainant and to all staff involved in the complaint.

8.5.2 If the complainant requires a letter this should be sent to Chief Investigator and those involved in investigation for comment. The letter should be signed by the Director of the Division or Institute.

8.5.3 If the complainant requires clarification of any point in the initial response, this will be undertaken by the Director of the Division or Institute.

8.5.4 If the complainant is still dissatisfied, then they must be informed that they may appeal in writing to the Chair of the UCL Clinical Research Governance Committee. Such an appeal must be submitted within 28 days of the announcement of the outcome of the initial investigation.

8.5.5 The Chair of the UCL Clinical Research Governance Committee will take such action as he/she deems appropriate to review the original investigation and decision. That review will most likely entail a detailed review of documentation provided to the original investigator. The Chair of the UCL Clinical Research Governance

Committee may choose to undertake additional actions as s/he sees fit, including, if deemed necessary, delegation of the review to a more appropriate Reviewer.

8.5.6 On completing the review, the Chair of the UCL Clinical Research Governance Committee (or the appropriately delegated Reviewer) will write to the complainant, with copies to the original investigator, the relevant Director of Division, the Managing Director of the Research Support Centre, the Director of Planning and Performance, the Head of Risk and Regulation in the Joint Research Office and the Vice Provost (Health) to set out their decision. The letter may address the appropriateness or otherwise of the process and/or content of the original investigation, and may support, amend or overturn any actions and/or recommendations set out in the initial investigation.

8.5.7 The appeal should be completed by the Chair of the UCL Clinical Research Governance Committee within 3 months of receiving an appeal from the complainant.

8.5.8 If investigation suggests that the complainant could potentially have a claim for negligence against UCL or the complaint indicates that s/he intends to make an insurance claim against UCL then the UCL Insurance Manager must be informed.

9. DOCUMENTATION RELATING TO THE COMPLAINT

In addition to copies held in the Division, Institute or CTU (under 8.4.1 above), copies of relevant the information/documentation, relating to the complaint will be held by the Joint Research Office.

10. DISSEMINATION

The policy will be disseminated through the Joint Research Office website, SLMS newsletter, by email to all Principal Investigators and made available to all relevant research Divisions, Institutes, and CTUs and support staff within UCL.

11. FEEDBACK ON THIS POLICY

The Joint Research Office welcomes feedback on the operation of this procedure as it is keen to learn and respond to local experiences. Any comments should be made by email to the Director of Research Support.

Flow diagram of Complainants procedure

