

Research Study Volunteer Complaints Procedure

The procedures involved in making a complaint about any aspect of a research study in which you have been involved are explained below.

The complaints procedure aims to:

- be easily accessible;
- allow speedy handling, with established time limits for action;
- ensure a full and fair investigation;
- respect the volunteer's desire for confidentiality as appropriate;
- address all the points at issue, and provide an effective response and appropriate redress;
- provide information to management so that services can be improved.

We hope you will find little to complain about while participating in any research study at the university but if you do bring concerns to our attention you can be sure that they will be treated seriously and every effort made to ensure their satisfactory resolution.

Scope of the procedure

The procedure can be used to complain about any aspect of treatment or procedure associated with research studies for which you have volunteered. This may include -

- ❖ Treatment by the research staff
- ❖ Treatment of your personal information by research staff
- ❖ Any aspect of the organisation of the study – i.e. competence of the researchers, timekeeping, ability to perform duties
- ❖ Any perceived deviation from the information given on the information sheet or consent form
- ❖ Concerns about ethical issues in the design or conduct of the study

Procedure

The procedure has three stages. The first stage allows for informal resolution, and only where this has proved unsuccessful or is thought to be inappropriate can Stage 2, which is the first of the two formal stages, be invoked.

Stage 1

It is hoped that most issues can be resolved if properly addressed at local level by research staff involved in the study. You are therefore encouraged to approach the relevant member of staff in the first instance. In order that a complaint can be dealt with effectively and efficiently it must be drawn to the attention of the member of staff concerned as soon as possible, and normally not later than five working days after the incident giving rise to the complaint. The complaint may be either oral or written and an appropriate response should be made to you, normally within 5 working days of receipt of the complaint.

If you believe the complaint to be sufficiently serious or you do not feel able to raise it directly with the member of staff concerned, then you should proceed directly to Stage 2.

Stage 2

In the event that you remain dissatisfied with the outcome of Stage 1 or if informal resolution is not appropriate, you may submit an oral or written complaint to the Head of School, Director of Research or their nominated individual using form CR1. This form asks you to provide details of the complaint and of any attempts made to resolve it informally.

Form CR1 should be completed within ten working days of the unsatisfactory outcome of Stage 1 and normally not later than 25 working days after the incident giving rise to the complaint.

You should receive a written response within 10 working days of the submission of the CR1 form and this should indicate what action has been taken or is proposed to resolve your complaint or, if your complaint is not upheld, the reasons for that decision.

With your permission the complaint will also be reported to in the University's Research Governance section to be recorded.

Stage 3

If on receipt of the written response from the Head of School or Director of Research you still consider that the complaint has not been adequately addressed you can write to the University Research Governance section, Form CR2 is available for reporting your complaint. This form asks you to provide details of the complaint and of the informal and formal efforts made to resolve it. Where it is evident that the second stage has not been followed you will be advised that the University must have the opportunity to consider and respond to the complaint before further action can be taken. Form CR2 must normally be completed within ten working days of receipt of the response from the Head of School or Director of Research at stage 2.

Following receipt of the complaint, the Research Governance section will arrange for a Complaints Review Panel to be established to consider and adjudicate upon the complaint and this meeting should normally take place within 30 working days of receipt of form CR2.

The Complaints Review Panel will have available to it all previous correspondence relating to the complaint and any other relevant documentation. The Panel will meet in private and may wish to ask you some questions in relation to your complaint. The Panel may also question any members of staff involved and will seek to establish all relevant facts before reaching a decision.

The conclusions of the Complaints Review Panel shall be communicated to you within 10 working days. The Complaints Review Panel will at the same time send a report summarising the complaint, the action taken to resolve it and their conclusions and recommendations to the Vice-Chancellor and to the relevant Dean or Head of Department. If the complaint is upheld, the Dean or Head of Department concerned will be asked to respond to the Vice-Chancellor and to the Chairman of the Complaints

Review Panel within 15 working days of receipt of the report stating what action has been taken or is proposed in the light of the Panel's recommendations.

All such contacts will be treated as confidential but it should be noted that the Research Governance section can offer advice on the procedures only and will not give an opinion on the complaint itself.

APPENDIX I

Procedures:

- a. Receipt by Research Governance of a copy of a completed CR1 form

Upon receipt by Research Governance of a copy of a completed CR1 form, this will be filed with the existing materials held for the study and will form part of the record for that study. The Research Governance section will also request, after the appropriate time has elapsed, a copy of the response to the complaint and any other related correspondence to ensure that the matter has been resolved and recorded.

- b. Receipt by Research Governance of a completed CR2 form

Upon receipt by Research Governance of a completed CR2 form the following steps will be taken:

- i. receipt of the form will be acknowledged to the complainant;
- ii. the appropriate Dean, Research Institute Director, the CI/PI and the PVC (R&I) will be informed that a formal (stage 3) complaint has been received and that a review panel will be established to investigate and adjudicate upon the complaint;
- iii. the Research Governance section will convene a review panel consisting of a lay member of the Council (chair), the Dean of a faculty not implicated in the complaint, the Director of a Research Institute not implicated in the complaint and a member of the Research Governance Steering Committee;
- iv. the review panel will request and receive all correspondence to date relating to the complaint and all appropriate materials relating to the complainant's involvement in the research project, including information sheets, consent forms and other relevant documentation;
- v. the review panel will review the documentation and may request additional comments or statements from the complainant or the researchers involved in the study;
- vi. the review panel will meet within 30 days of the date of receipt of the CR2 form by the Research Governance section and will review all of the documentation submitted by the complainant and by the researchers;
- vii. the review panel will reach a decision upon whether or not the complaint is upheld;
- viii. if the complaint is upheld:
 - the review panel will write to the Dean of the faculty concerned recommending appropriate action;

- the Dean will undertake the recommended action and respond to the panel within 5 working days to indicate that the action is being taken;
 - the review panel will write to the complainant indicating the outcome of the review and the action being taken.
- ix. if the complaint is not upheld, the review panel will write to the complainant and all others involved indicating that following a full investigation, the complaint has not been upheld and no further action will be taken.

Appendix II

Research Study Complaints Procedure CR1

This form should be used for complaints involving research projects. Please read the Research Study Complaints Procedure leaflet before completing this form.

Every effort will be made ensure confidentiality, consistent with a full investigation of any complaint.

1. Name of complainant	
2. Address for correspondence	
3. Research Study Title	
4. Principal/Chief Investigator	
5. Researcher(s)	

6. Details of the complaint (please ensure that all relevant details are provided, attach additional sheets if necessary).

7. Please summarise any informal action taken to resolve the complaint or explain why informal action was not considered to be appropriate:

I understand that a copy of this form will be provided to any member of staff who is the subject of the complaint, or who is otherwise involved.

Signed_____ Date:_____

Completed forms should be returned to:

The relevant Head of School, Research Institute Director or their nominee.

Research Study Complaints Procedure CR2

This form should be used for complaints involving research projects. Please read the Research Study Complaints Procedure leaflet before completing this form.

Every effort will be made ensure confidentiality, consistent with a full investigation of any complaint.

1. Name of complainant	
2. Address for correspondence	
3. Research Study Title	
4. Principal/Chief Investigator	
5. Researcher(s)	

6. Details of the complaint (please ensure that all relevant details are provided, attach additional sheets if necessary).
7. Please summarise any informal/formal action taken to resolve the complaint:

8. Reason for continued dissatisfaction:

I understand that a copy of this form may will be provided to any member of staff who is the subject of the complaint, or who is otherwise involved.

Signed _____ Date: _____

Completed forms should be returned to:

Research Governance
Room 01H12
[Research Office](#)
University of Ulster
Jordanstown campus
Shore Road
Newtownabbey
Co. Antrim
BT37 0QB