Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Complaints from Research Participants**		
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	Name and Position	Signature	Date
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* For all University sponsored research recorded as risk category level 4, including IMP studies
\# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Draft v 2.0
Draft v 2.0	20/10/11	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	21/08/12	Periodic Review	Final v 3.0
Final v3.0	10/10/12	Amended to include research regulated by the Human Tissue Act 2004	Final v4.0
Final v 4.0	23/10/2014	Periodic Review	Final v 5.0
Final v 5.0	18/01/2017	Periodic Review	Final v 6.0

1. Purpose

This Standard Operating Procedure (SOP) provides guidance to researchers as to how to manage complaints/concerns made by the participants in a research study.

2. Introduction

Informed consent is at the heart of ethical research. A core ethical principle is that every researcher must respect each individual research participant. All participants entering into a research project/clinical study must give their informed consent before they can become involved and this must be ongoing throughout the life of the study.

Part of informed consent is the provision of information sheets to research participants. These information sheets should, as specified by the Health Research Authority (HRA) guidance on information sheets and consent forms, version 3.5 May 2009,

".....should describe how any complaints will be handled and what compensation may be available in the event of someone being harmed. This information must be applicable to the setting in which the research will be conducted eg University, NHS ..."

A complaint can be received by any member of a research team either verbally or in writing.

3. Scope

This procedure applies to all research conducted involving human subjects for which the University is either Sponsor or co-sponsor, including research regulated by the Human Tissue Act 2004 (HT Act).

4. Responsibilities

4.1 Chief Investigator

Overall responsibility for all elements of research activity, including the provision of information as part of the informed consent process and the conduct of the study, rests with the Chief Investigator (CI). The CI must ensure that the research study is conducted in accordance with the protocol and the ethical approval.

In the event of a complaint/concern being raised by a research participant, the CI must ensure that the complaint/concern is handled in accordance with the information provided in the participant information sheet.

The CI is also responsible for implementing any remedial action that arises from an investigation into a complaint/concern.

5. Procedure

5.1 Information Sheets

Participant information sheets should provide the name and contact details of the person to be contacted in the event that a research participant wishes to raise a concern about any aspect of the research study.

5.2 Processing a complaint

A complaint or concern can be raised with any member of the research team.

On receipt of a complaint or concern, the member of the research team must record the detail on the complaint form, attached as appendix 1.

Using the information received and the researcher's knowledge of the study, the research team must assess the complaint/concern to:

- Determine whether it is related to a serious event in relation to the study procedure (Serious Adverse Event (SAE)); or
- How the participant has been treated whilst taking part in the study.

In the event of an SAE the SOP for Adverse Events (QUB-ADRE-006) should be followed.

If, following assessment, the issue raised is deemed to be a complaint it must be dealt with as specified in the participant's information sheet. Where the complaint relates to the clinical/social care of a patient/client, the Complaints Department of the relevant Trust must be advised within 24 hours of the complaint being received. Should the complaint be related to the research practice, the CI must discuss the complaint with the research participant and agree an appropriate approach. This should include:

- How the complaint will be dealt with;
- An approximate timeline for dealing with the complaint, which ideally should be no longer than 20 working days;
- Who will be involved investigating the complaint;
- Any immediate action required to remedy the issue raised.

In the event that the complaint explicitly makes reference to legal action or if it is the view of the CI a legal opinion could be necessary, the complaint must be brought to the attention of the University's legal services team.

5.3 Complaint resolution

Once the complaint has been investigated the CI, or a suitable designated individual, must meet with the participant and discuss the findings and any proposed remedial action.

The complainant can determine whether they are satisfied with the outcome of the investigation and the proposed remedial action, if appropriate. If the complainant remains dissatisfied the CI should discuss the complaint with the Head of Research Governance (HRG). For research studies regulated by the HT Act the CI must also inform the Designated Individual of any unresolved complaints.

The HRG, in conjunction with the Director of Research and Enterprise will determine if further formal investigation is required. The HRG will inform the complainant in writing of the decision and advise the complainant of the timescale required to carry out any formal investigation, if deemed necessary.

Once completed, the HRG will inform the complainant of the outcome in writing.

6. References

HRA guidance on information sheets and consent forms (last accessed January 2017).
http://www.hra-decisiontools.org.uk/consent/
Human Tissue Authority (last accessed January 2017)
http://www.hta.gov.uk/

Queen's University Belfast, Standard Operating Procedure, Informed Consent SOP-ADRE-004.

Appendix 1

Raising a concern or complaint

		Date & initial
Research Study:		
Chief Investigator:		
Name and address of complainant:		
Date concern/complaint raised:		
Nature of complaint:		
Decision as to whether SAE or complaint:		
If deemed a complaint:		
Process agreed with complainant:		
Summary of investigation findings:		
Remedial Action (if required):		
Outcome of complaints		

meeting:		
Further actions (if required)		

Signed _____ (Chief Investigator, or local PI).

Date _____

Copy to: Site master file
Head of Research Governance
Designated Individual (for Human Tissue Act 2004 regulated research studies only)