Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster CCG	Page 1 of 5
Research Management & Governance	SOP No. RM&G0012, Version 1
Serious Breaches of GCP or Study Protocol	Supersedes: Not applicable
	Attachments: None
	Effective date: 13th September 2013

Signatures:

Role	Name	Function	Date (DD-MM-YYYY)	Signature
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1.0 Definitions

Please refer to the current version of the SOP RM&G0002 for a glossary of all terms and acronyms.

Serious breach - a breach which is likely to effect to a significant degree the safety or physical or mental integrity of the subjects of the trial; **or** the scientific value of the trial.

(Glossary taken from Medicines for Human Use (Clinical Trials) Regulations 2004)

2.0 Purpose

The purpose of this SOP is to cover the procedures surrounding the recording, management and reporting of all serious breaches. All serious breaches should be recorded and reported to the Sponsor, who will take the appropriate action of notifying the Research Ethics Committee (REC) in accordance with the necessary requirements. For Clinical Trials of Investigational Medicinal Products (CTIMPs), in addition to reporting to the REC, the Medicines and Healthcare Products Regulatory Agency (MHRA) must be notified as the licensing authority, in accordance with regulation 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 [Statutory Instrument 2004/1031], as amended by Statutory Instrument 2006/1928.

3.0 Scope

This SOP covers all personnel who are involved in research studies taking place within Doncaster and Bassetlaw Hospitals NHS Foundation Trust. The procedure described in this SOP should be followed when a breach of Good Clinical Practice (GCP) or the study protocol is identified in:

(i) a research study hosted, but not sponsored, by Doncaster and Bassetlaw Hospitals NHS Foundation Trust

(ii) a non-CTIMP research study sponsored by Doncaster and Bassetlaw Hospitals NHS Foundation Trust *(The Trust does not currently sponsor CTIMPs)*

4.0 Procedure

It remains the responsibility of the Chief Investigator and Principal Investigator(s) to ensure that all aspects of the research is undertaken in accordance with GCP standards and the study protocol. In cases where aspects of this responsibility are delegated to a suitably qualified or experienced member of the research team, this should be clearly documented in the delegation log held within the site file.

For all studies, monitoring will be conducted in accordance with the specific arrangements made by the Sponsor. In addition to the sponsorship monitoring arrangements, Doncaster and Bassetlaw Hospitals NHS Foundation Trust may audit the study as part of their Quality Assurance procedures.

Persistent and systematic non-compliance with GCP or the protocol, such as repeated protocol deviations, may constitute a serious breach. It should be noted that not every Serious Adverse Event (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR) would routinely be classified as a serious breach.

4.1 Documenting breaches of GCP or Protocol

Once identified, all breaches of GCP or the study protocol must be clearly documented in the case report form, a site file note or a Sponsor specific form to ensure appropriate corrective and preventative actions can be taken. Documentation of the breach should include as a minimum:

(i) details of the breach including date and time of occurrence
(ii) any remedial action undertaken
(iii) assessment by the Chief Investigator or Principal Investigator (or delegated member of research team) as to whether the breach is serious (include signature, date and time)
(iv) any information given to participants

4.1 Reporting breaches of GCP or Protocol

4.1.1 An externally sponsored research study hosted by Doncaster and Bassetlaw Hospitals NHS Foundation Trust

Where a Principal Investigator or delegated member of research team (delegate) identifies or is notified of a serious breach, the following procedures must then be followed:

1. The Principal Investigator or delegate reports the serious breach to the Sponsor, in accordance with the protocol specified requirements. If investigation or corrective and preventative action is ongoing at the time of reporting the serious breach, it is acceptable to indicate your plans with projected timelines for completion.

2. The Principal Investigator or delegate must notify the Research Management and Governance Manager or the Clinical Research Development Manager, that a serious breach has occurred within 24 hours of the breach being identified. The Principal Investigator (or delegate) must provide any additionally requested information, within the Sponsor specified timeframe.

3. A copy of the information provided to the Sponsor should be sent to the Research office via fax: 01302 553254. The Research Governance team will acknowledge receipt of the faxed notification of breach by the close of business the next working day. Acknowledgement will be faxed to the fax number from which the breach was notified unless an alternative method of acknowledgement has been agreed with the Research office in writing. It is the responsibility of the reporting individual to contact the Research office if no acknowledgement is received by the close of business the next working day.

4. Upon receipt of a fax notifying a serious breach, the member of staff receiving the notification will immediately inform the Research Management and Governance Manager or the Clinical Research Development Manager (whichever available at the time of receipt).

5. The Director of Research and Development will be informed of all serious breaches. The Research office will make a decision on the continuation of the study in relation to the reported event, based on risk. The Research office reserves the right to withdraw or suspend Trust approval for any research study, where there are safety concerns about the continuation of the study. Where a decision is made to temporarily suspend the study, the Principal Investigator and Sponsor will be notified in writing.

6. All information must be filed in the Investigator Site File.
7. Any follow up information should be provided in the sponsor specified timeframe.

4.1.2 A non-CTIMP research study sponsored by Doncaster and Bassetlaw Hospitals NHS Foundation Trust *(The Trust does not currently sponsor CTIMPs)*

Where a Principal Investigator or delegated member of research team (delegate) identifies or is notified of a breach, the following procedures must then be followed:

1. The Principal Investigator or delegate must send a faxed report to the Trust Research office on 01302 553254, containing all information as stated in section 4.1. This should be within 24 hours of the breach being identified. If investigation or corrective and preventative action is ongoing at the time of reporting the serious breach, it is acceptable to indicate your plans with projected timelines for completion. The Principal Investigator (or delegate) must provide any additionally requested information, within the Sponsor specified timeframe.

2. The Research Governance team will acknowledge receipt of the faxed notification of breach by the close of business the next working day. Acknowledgement will be faxed to the fax number from which the breach was notified unless an alternative method of acknowledgement has been agreed with the Research office in writing. It is the responsibility of the reporting individual to contact the Research office if no acknowledgement is received by the close of business the next working day.

3. Upon receipt of a fax notifying of a serious breach, the member of staff receiving the notification will immediately inform the Research Management and Governance Manager or the Clinical Research Development Manager (whichever available at the time of receipt).

4. The Research Management and Governance Manager or the Clinical Research Development Manager will discuss the breach with the Chief Investigator/Principal Investigator and study team, to reach a decision as to whether the breach is serious in nature. This assessment will be documented in the Sponsor File.

5. All serious breaches will be discussed with the Director of Research and Development. The Research office will make a decision on the continuation of the study in relation to the reported event, based on risk. The Research office reserves the right to withdraw sponsorship and withdraw or suspend Trust approval for any research study, where there are safety concerns about the continuation of the study. Where a decision is made to temporarily suspend the study, the Chief Investigator/Principal Investigator will be notified in writing.

6. The REC will be notified of the serious breach within 7 days of the breach having been identified, in the REC specified format. The report will be completed by the Research Governance team.

7. All information must be filed in the Investigator Site File.

4.2 Urgent Safety Measures

In accordance with the Clinical Trials Regulations, the Chief Investigator, Principal Investigator or Study Sponsor may take appropriate urgent safety measures in order to protect the participants of a

CTIMP against any immediate hazard to their health or safety, without prior approval from the regulatory bodies or Trust Research and Development Department.

Related SOPs and Documents

1. No associated SOPs at this time