Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Termination or Suspension of a Research Study**		
SOP Reference Number:	QUB-ADRE-020	Date prepared	13 August 2008
Version Number:	Final v 5.0	Revision Date	18 January 2017
Effective Date:	1 November 2008* 1 December 2009#	Review Date:	December 2018

	Name and Position	Signature	Date
Author:	Mrs Louise Dunlop Head of Research Governance	Louise Dunlop	29-03-2017
Reviewed by:	Professor James McElnay, Chair Research Governance and Integrity Committee	James McElnay	22-03-2017
Approved by:	Mr Scott Rutherford Director, Research and Enterprise	Scott	15. 3. 2017

This is a controlled document.
When using this document please ensure that the version is the most up to date by checking the Research Governance Website

* 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	09/09/11	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 v 3.0	06/10/2014	Periodic Review	Final v 4.0
Final v 4.0	18/01/2017	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) provides guidance in the event of a research study being suspended or terminated early.

The primary focus of this SOP is for clinical trials of IMPs but it is relevant for any research being undertaken under the auspices of the University.

2. Introduction

Where a Sponsor/co-sponsor raises concerns regarding the conduct of a clinical trial, the Sponsor may suspend the recruitment to the trial until the concerns raised have been satisfactorily addressed.

Alternatively the Chief Investigator (CI) may have concerns and deem it necessary to suspend or terminate a clinical trial, in which case the CI must advise the lead Sponsor. Where a trial is suspended without prior agreement of the Sponsor, the Chief Investigator must inform the institution and/or Sponsor immediately, and no later than 1 working day from the time of suspension.

The main Research Ethics Committee (REC) may terminate or suspend its approval/favourable opinion of a trial. In these circumstances the CI must inform the institution and/or Sponsor(s) immediately, and no later than 1 working day from the time of suspension.

In the event of a trial being suspended or terminated, it is a legal requirement under the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments that the Sponsor, or someone acting on behalf of the Sponsor must notify the Medicines and Healthcare products Regulatory Agency (MHRA) (if applicable) and the Research Ethics Committee (REC) and clearly explain the reasons for the suspension/termination.

3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

4. Responsibilities

4.1 Chief Investigator

The CI is responsible for ensuring that the clinical trial is conducted in accordance with the protocol. In the event of an issue being raised within the trial or by the Sponsor resulting in a trial suspension/termination, the CI must ensure that the appropriate authorities are notified. In addition, the CI should promptly inform the trial subjects providing assurances that the appropriate therapy and follow-up will be available.

5. Procedure

5.1 Suspension/Termination by Sponsor

If the Sponsor suspends/terminates a trial, the CI must promptly inform the institution(s) where the trial is being conducted. The CI must also inform the main REC within 15 days of the date of the termination and provide them a detailed written explanation of the termination/suspension.

5.2 Suspension/Termination by CI

If the CI suspends/terminates a trial without prior agreement of the Sponsor, the CI must inform the institution(s) where the trial is being conducted. In addition, the CI must promptly notify the Sponsor within 1 working day of the trial's suspension/termination and also notify the REC as outlined in 5.1 above.

5.3 Suspension/Termination by REC

If the main REC suspends/terminates its favourable opinion of a trial, the CI must inform the institution(s) where the trial is being conducted and notify the Sponsor as outlined in 5.2 above.

5.4 Research Subjects

Where possible, the CI should promptly inform the trial subjects of the suspension/termination of the trial and provide assurances to them regarding their therapy and follow-up. The need for this should be discussed and agreed by the Clinical Trial Steering Group, if applicable.

5.5 Other Investigators

The CI should inform other investigators involved in the trial of the suspension/termination. In the event of the termination the letter should:

- Thank the investigator for their participation;
- Summarise patient status;
- Remind the investigator(s) of their continuing trial obligations e.g. archiving;
- Arrange the return of trial supplies, if applicable;
- Advise the possibility of audit or inspection, if applicable;
- Outline the results of the trial or provide a copy of the trial report;
- Inform the investigators, if possible, of the expected timing of publication.

5.6 Non-Commencement / Early termination

If the Sponsor decides not to commence or recommence a trial after halting it, the competent authority and ethics committee should be notified using the End of Trial Form. A covering letter should be sent that identifies the protocol, its protocol code number and the EudraCT number. A brief explanation of the reasons should also be provided. The End of Trial form can be found at: http://ec.europa.eu/health/documents/eudralex/vol-10/ (last accessed January 2017) as detailed in SOP QUB-ADRE-012.

When a trial is terminated early, the end of clinical trial report should also provide the following information:

- Justification of the premature ending of the trial;
- Number of patients still receiving treatment at the time of study's termination;
- Proposed management of the patient receiving treatment at the time of the study termination;
- Consequences for the evaluation of results.

6. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice EB (R1): http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf (last accessed January 2017)

DoH Clinical Trials Toolkit (last accessed January 2017) http://www.ct-toolkit.ac.uk/