Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**End of Study Declaration**		
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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	18/08/11	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	19/09/2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process for notifying the MHRA and/or Research Ethics Committee and the University that a research study has ended.

2. Introduction

The definition of the end of the trial should be provided in the protocol and any change to this definition, for whatever reason, notified as a substantial amendment. In most cases the end of the trial will be the date of the last visit of the last patient undergoing the trial.

The Medicines for Human Use (Clinical Trials) Regulations 2004 and the Health Research Authority National Research Ethics Service, locally the Office of Research Ethics Committees Northern Ireland, state that the MHRA and the REC be notified within 90 days of the end of a project, or within 15 days if the project is terminated early.

3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor.

4. Responsibilities

4.1 Chief Investigator

The Sponsor is responsible for making an end of study declaration. Where the University is acting in the capacity of Sponsor this responsibility is delegated to the Chief Investigator (CI).

The CI should be same person who submitted the clinical trial authorisation to the MHRA and/or the application to the REC, unless otherwise notified as a substantive amendment (SOP QUB-ADRE-011).

5. Procedure

5.1 Notification of an end of Study in Clinical Trials of Investigational Medicinal Products

The MHRA and REC must be notified that a study has ended within 90 days of the end of the clinical trial. This notification must be made on the appropriate form, accessed through the Eudralex website:
http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm
(last accessed September 2016). The following information should be provided:

- Name and address of the sponsor;
- Trial title;
- EudraCT number;
- Sponsor's protocol code number;
- Date of end of trial in the Member State concerned;
- Date of end of complete trial in all participating centres in all countries when available.

5.1.1 Premature end of a trial

Whenever a trial is terminated early, the MHRA and REC must be notified immediately and at least within 15 days from when the trial is halted. This should be notified using the Declaration of End of Trial form, as outlined above.

In this case the end of clinical trial report should also provide the following information:

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

5.2 Final Report on the Research

A summary of the final report on the research should be sent to the main REC within 12 months of the end of the project. There is no standard format for final reports. However, the REC should be advised whether the project achieved its objectives, the main findings and arrangements for publication or dissemination of the research, including any feedback to participants.

6. References

Medicines and Healthcare products Regulatory Agency website, last accessed September 2016. https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues.

Eudralex Volume 10 (last accessed September 2016): Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use