LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1038 LU

End of Study Reporting Requirements for NHS Research Studies Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

This Standard Operating Procedure (SOP) describes the processes required at the end of a research study. There are reporting obligations in addition to ensuring transparency of research study data.

There is an expectation that study data be published including a summary of results on a publically accessible register. In addition, there are regulatory requirements to submit final study reports to Loughborough University (LU) Research Governance Officer and the REC.

2.0 Scope

This SOP applies to all research studies covered by the Research Governance Framework (v2 2005) that are sponsored by LU.

3.0 Definition

The reporting requirements are triggered from the date of the end of the study which should be provided in the protocol. In most cases it will be the date of the last visit of the last subject undergoing the trial. The end of the recruitment period does not automatically signify the end of the trial.

4.0 End of Study Notification

It is the responsibility of the CI to complete the appropriate forms at the end of the study and submit these to the REC which gave a favourable opinion of the research as appropriate. A copy should also be sent to the Sponsor.

4.1 Notification to the REC

The appropriate form should be sent within 90 days of the end of the study. The Sponsor does not have a separate form to complete. The forms published on the HRA website should be used.

5.0 Early Termination or Abandoned Studies

If a study is terminated early for any reason, including lack of recruitment or lack of funding, the CI (or Sponsor) must notify the REC within 15 days of the date of termination with an explanation of the reasons for the early termination, with a copy to the Sponsor. Where it is necessary to seek ethical review of related actions such as informing subjects and arranging continuing care and follow up outside the study, a notice of substantial amendment could be submitted alongside the declaration of early termination.

If a study is abandoned prior to commencement the CI or Sponsor should notify the main REC in writing, outlining the reasons for abandoning the study.

6.0 Final Report on the Research

A summary of the final research report should be sent to the REC within 12 months of the end of the study. Production of the report is the responsibility of the CI who should submit it on completion to the Sponsor who will then forward it to the REC. There is no standard format for final reports. As a minimum, it should include information about whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

7.0 Participants at the End of Study

At the end of the research study it is expected that all commitments made to the participants as described in the IRAS application, the protocol and the Patient Information Leaflet will be fulfilled. This may include care after research and/or providing information about the outcome of a study.

8.0 Publication and Dissemination

Researchers and Sponsors are expected to ensure, as a minimum that research is registered and summary results are published on a suitable publicly-accessible register. Reference to the IRAS ID number should be made in publications and reports to allow tracking of transparency commitments made to the funder and REC.

The requirements of the Health Research Authority (HRA) to ensure transparency are in development at the time of publication of this SOP and it is advised that their website is consulted to ensure Sponsor obligations are fulfilled.

http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/transparency/

9.0 Responsibilities

	Responsibility Undertaken by		Activity
1	CI	CI or delegate	Complete End of Study Notification form and submit to the REC within 90 days of the end of study with a copy to the Research Governance Officer.
2	CI	CI or delegate	Produce a final research report and submit to the Research Governance Officer.
3	LU Research Office	Research Governance Officer or delegate	Submit the final research report to the REC within 12 months of the end of the study.
4	CI	CI or delegate	Fulfil obligations made to participants regarding the end of the study.
5	CI	CI or delegate	Fulfil the requirements of the Health Research Authority (HRA) regarding transparency of research results.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions:

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	Ethics Committee	**Date Approved: 23/10/15**

REVIEW RECORD			
Date	**Issue No.**	**Reviewed By**	**Description Of Changes (If Any)**

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