LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1022 LU

Process for Submission of Annual Progress Reports for NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 Introduction

This SOP details the procedures for managing the submission of Annual Progress Reports (APRs) for research studies where Loughborough University (LU) is acting as the Sponsor Organisation.

It is a condition of Research Ethics Committee (REC) Favourable Opinion and is included in the Chief Investigator Responsibilities document (which is signed by the Chief Investigator prior to confirmation of Sponsorship by LU), that a progress report will be submitted to the REC and the Sponsor on the anniversary of REC Favourable Opinion, and annually thereafter until the End of Study Declaration has been submitted.

2.0 Procedure

The Sponsor will alert the Chief Investigator at least one month before the APR is due to be submitted. A reminder email will be sent every four weeks after the due date for up to three occasions (3 months).

An annual progress report is required on the anniversary of the REC Favourable Opinion. The Chief Investigator must complete the relevant Annual Progress Report form (APR) and submit it to the Sponsor for review and authorisation prior to submission to the REC.

Once authorised by the Sponsor, the APR can be submitted by the Chief Investigator to both the REC where the original Favourable Opinion was first given and, where required, to NHS Trust R&D Offices and copied to the Sponsor.

The completed APR must be retained in the Trial Master File along with any acknowledgement correspondence received from the REC, NHS Trust R&D Offices and the Sponsor.

Template forms can be accessed on the Health Research Authority Website

Multi-Centre Studies

In cases of multi centre research studies, it is essential to include safety information from all sites and not just the main site.

Non-CTIMPs

Any serious adverse events (SAEs) must be included as a Line Listing for the whole study, including information from all sites.

3.0 Non-Compliance

Failure to submit APR within three months of the due date (or after three reminders sent from the Sponsor) will result in the Non-Compliance SOP-1016 LU being implemented, with action being taken at a Critical level.

4.0 Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Research Governance Officer or their delegate	Send alert 1 month prior to APR due date
2	Chief Investigator	Chief Investigator or their delegate	Submit appropriate APR to the Sponsor for review and authorisation
3	Sponsor	Research Governance Officer or their delegate	Once satisfied, authorise submission to relevant regulatory authorities
4	Chief Investigator	Chief Investigator or their delegate	Submit to relevant regulatory authorities and file signed APR and all correspondence in TMF
5	Sponsor	Research Governance Officer or their delegate	Initiate Non-Compliance SOP if no APR received

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: 5/2/16**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

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