1. Introduction

This Standard Operating Procedure (SOP) details the procedures for managing the submission of Annual Progress Reports (APRs) for research studies where the University Hospitals of Leicester NHS Trust (UHL) 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 the UHL), 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.

In addition, research studies of Clinical Trials of Investigational Medicinal Products (CTIMP) are required to submit a Development Safety Update Report (DSUR) on the anniversary of the Clinical Trial Authorisation (MHRA Approval). The DSURs are dealt with separately in SOP S-1004 UHL. Where a DSUR is required, it is strongly recommended that you choose ONE date as your deadline to submit the first annual report & DSUR, then continue with that synchronised date throughout the duration of the research. This means that you will potentially submit one of the reports early but you are less likely to omit their submission in the future. In addition, it is strongly recommended that you document the review / amendment of the Investigator Brochure (IB)/ Summary of Product Characteristics (SPC) at the same time as detailed in SOP S-1023 UHL.

2. Scope

This SOP applies to all research Sponsored by the UHL

3. Procedure

The Sponsor will alert the Chief Investigator (CI) 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 CI 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 CI to both the REC where the original Favourable Opinion was first given and, where required, to the HRA & NHS Trust R&I Offices and copied to the Sponsor.

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

Template forms can be accessed on the **Health Research Authority Website**.

3.1 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.

3.2 CTIMPs

The SAE listings must be included in the DSUR which must accompany the APR

3.3 Non-CTIMPs

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

4. 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 S-1016 UHL being implemented, with action being taken at a Critical level.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Head of Research Operations 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	Head of Research Operations 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
4	Sponsor	Head of Research Operations or their delegate	Initiate Non-Compliance SOP if no APR received

6. Supporting Documents and Key References

SOP S-1004

SOP S-1023

SOP S-1016

7. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, ICH GCP, TMF, Annual Progress Report, AR

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

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Reviewed by:	R&I Governance Meeting	
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
April 2015	2	Carolyn Maloney	Change of name and Logos updated
July 2016	3	CM, LW,JJ	HRA changes. Consistency check.
February 2017	4	Carolyn Maloney	Update to Logo
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