



University of Leicester and University Hospitals of Leicester NHS Trust joint Research Support Office Standard Operating Procedures

University of Leicester (UoL) Research Governance Office

SOP S-1022 UoL

Process for Submission of Annual Progress Reports for Research Sponsored by University of Leicester

Office Base

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Effective Date: September 2023

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) details the procedures for managing the submission of annual reports for research studies sponsored by the University of Leicester (UoL).

2.0 Procedure

1. The Research Governance Office will contact the Chief Investigator (CI) and/or their delegate(s) annually and in advance of the submission deadline.
2. Reminders for the submission of the annual progress report will be sent approximately 1 month before the submission deadline. Overdue reminders will be sent where reports have not been submitted within the deadline.
3. The CI (their delegate(s)) fill in the relevant annual progress report form(s).
4. The CI (their delegate(s)) submit the completed annual progress report form(s) to rgosponsor@le.ac.uk

It is a condition of NHS Research Ethics Committee (REC) Favourable Opinion, that an annual progress report (APR) is submitted on the anniversary of REC Favourable Opinion until the End of Study Declaration has been submitted.

A copy of the APR should be sent to the REC who granted the Favourable Opinion, rgosponsor@le.ac.uk, and where required, the Health Research Authority (HRA), the Medicines and Healthcare products Regulatory Agency (MHRA)/Competent Authority and host NHS Trust R&D/I office(s).

Completion and submission of the appropriate APRs within the required reporting timelines is the responsibility of the Chief Investigator (CI) and is listed within the CI Roles and Responsibilities document which is signed by the CI prior to confirmation of Sponsorship. APRs are required for studies more than two years in duration and for Research Tissue Banks and Research Databases. Progress reports are not required for Proportionate Review studies.

For research studies with HRA approval and University of Leicester Ethical approval, a progress report will be submitted to the HRA in line with above.

Template forms can be accessed on the [HRA Website](#)

Sponsor may request an SAE line listing at the point of APR submission for reconciliation purposes. This should include SAEs experience at all sites in multi-centre studies.

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

2.1 Clinical Trials of Investigational Medicinal Products (CTIMPs)

In the case of CTIMPs, a copy of the REC APR must be submitted to rgosponsor@le.ac.uk for review and authorisation **prior to** submission to the REC.

In addition, CTIMPs are required to submit a Development Safety Update Report (DSUR) on the anniversary of the Clinical Trial Authorisation (MHRA Approval) For further guidance on DSUR submission refer to SOP S-1014. Where a DSUR is

required, it is strongly recommended that you choose **one** date as your deadline to submit both the first annual progress report and 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 (SmPC) at the same time (for further information refer to SOP S-1023).

2.2 Studies with Confidentiality Advisory Group (CAG) support.

For research studies involving Confidentiality Advisory Group (CAG) support, an annual review is required from date of the initial support letter. The CAG annual review must be completed and submitted annually to CAG and rgosponsor@le.ac.uk four weeks prior to the anniversary date of CAG support. This must continue until the End of Study Declaration has been submitted. For an annual review to be valid there must also be evidence that the relevant Data Security Protection Toolkit (DSPT) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Completion and submission of the CAG APR to both CAG and rgosponsor@le.ac.uk is the responsibility of the CI.

2.3 Funder reports

In addition to the reports listed above, depending on the funder of your research, there may be a requirement to submit annual (or other) progress reports. Please familiarise yourself with the requirements for your research study.

3.0 Non-compliance

Failure to submit an APR within three months of the due date may result in the Non-Compliance [SOP S-1016 UoL](#) being implemented, with action being taken at a Critical level.


4.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or their delegate	Send email reminder 1 month prior to APR due date
Chief Investigator	Chief Investigator or their delegate	Submit appropriate APR to the Sponsor for review and authorisation (CTIMP studies)
Sponsor	Head of Research Governance or their delegate	Once satisfied, authorise submission to relevant regulatory authorities (CTIMP studies)
Chief Investigator	Chief Investigator or their delegate	Submit to relevant regulatory authorities and file signed APR and all correspondence in TMF

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

5.0 Development and approval Record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	31 August 2023

6.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	RSMOG	Included Scope section, minor administrative changes to include R&I and changes to version and date in footer. Addition of Loughborough University to front page
Oct 2016	3	Diane Delahooke	Logo and HRA changes.
September 2021	3.1	Cat Taylor	Administrative changes
July 2023	4.0	Cat Taylor	Update to studies which are exempt from APR reporting Update to details regarding CI reminders for APR reporting Guidance added regarding CAG annual reporting Guidance added around funder progress reports Administrative changes