University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1022 UoL

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

Version 5.1 September 2024

Effective Date: September 2024

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 progress reports for research studies sponsored by the University of Leicester (UoL).

2.0 Procedure

Depending on what approval(s) you have received, you may be required to complete a progress report. Please be aware that where there are several different approvals in place from different regulatory bodies, you may be required to complete a progress report for all, some, or none of the regulatory bodies.

The webpages for the relevant regulatory body(ies) should be consulted for the most up to date guidance on submitting progress reports and to download the required template(s).

The procedure in all cases (with the exception of funder progress reports, see Section 3.5) will be:

1. The Chief Investigator (CI) and/or their delegate(s) will receive notification of progress report requirements in advance of the submission deadline from the Research Governance office/via Infonetica.
2. Reminders will be sent regularly before the submission deadline.
3. The CI (their delegate(s)) must fill in the relevant progress report form(s) (downloaded from the HRA webpage/relevant regulatory body webpage).
4. The CI must authorise the form.
5. CTIMPs/Medical Device Trials only: The CI (their delegate(s)) must submit the completed progress report form(s) to rgosponsor@le.ac.uk for review and approval prior to Step 6.
6. The CI (their delegate(s)) must submit the completed progress report form(s) to the relevant regulatory body(ies) with rgosponsor@le.ac.uk copied in.
7. Overdue reminders will be sent where reports have not been submitted by the deadline.
8. Completed progress reports must be retained in the Trial Master File (TMF) along with all correspondence.
9. Repeat the above steps annually until the End of Study Declaration form has been submitted.

3.0 Additional Information

3.1 NHS Research Ethics Committee (REC) Approval

From 1st August 2024 studies with NHS REC approval are no longer required to submit REC annual progress reports.

3.2 University Ethics Approval

For studies with University of Leicester Ethical approval, a progress report is not required.

3.3 Confidentiality Advisory Group (CAG) Approval

An annual review report should be submitted to the Confidentiality Advice Team by email four weeks before the approval expires (i.e., no later than 11 months following the approval date). Current guidance and the report template should be downloaded from

the HRA Progress Report webpage: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/.

NOTE: Evidence of suitable security arrangements must be in place before any support can come into effect, and must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS England at each annual review. Please ensure you have factored in enough time for reviewing/renewing security arrangements.

3.4 Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Trials

CTIMPs are required to submit a Development Safety Update Report (DSUR) (or 'safety report') on the anniversary of the Clinical Trial Authorisation (MHRA Approval). For further guidance on DSUR completion refer to SOP S-1014. 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).

The MHRA Clinical trials webpage should be consulted for the most up to date guidance on submitting progress reports (see the 'Developmental Safety Update Reports' section).

https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#submit-development-safety-update-reports-dsurs

In addition, the HRA Safety and progress reports for CTIMPs procedural table can also be consulted:

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/safety-and-progress-reports-ctimps-procedural-table/

3.4.1 CTIMPs approved via the Combined Review Process

Reports for CTIMPs (and combined CTIMPs + Medical Device trials) that were approved by combined review should be submitted via the Combined Review IRAS platform. If the report requires action, the MHRA will instruct the study team to submit a substantial amendment to the REC.

If at least one of the trials covered by the DSUR has gone through the Combined Review process, then the DSUR must be submitted via the Combined Review IRAS platform. The DSUR must not be submitted again via MHRA Submissions to account for the other trials that have not been approved by Combined Review.

Please use the Quarterly Summary Reports template for providing the summary for the medical device aspect of the trial (if applicable). See Section 3.4.3 below.

More information can be found on the Health Research Authority (HRA) website.

3.4.2 CTIMPs approved via the non-Combined Review Process

Submit your DSUR using MHRA Submissions via the Human Medicines Tile. Please select 'Development Safety Update Report' as the Regulatory Activity and 'Original Submission' from the Regulatory Sub Activity dropdown list. Acknowledgements of receipt are generated by MHRA Submissions where a confirmation of submission is emailed to the reporter.

Separately, the DSUR should be emailed to the approving REC with the CTIMPs Safety Report form as the cover sheet. An acknowledgment receipt of all safety reports will be issued by email within 30 days. Reports sent without the CTIMP safety report form cover sheet will not be acknowledged.

The HRA Safety Reporting webpage should be consulted for the most up to date guidance on submitting progress reports:

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/

3.4.3 Medical Device Trials

The MHRA Medical Device webpage should be consulted for the most up to date guidance on submitting progress reports (see the 'Quarterly summary reports' section).

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

A Quarterly Summary Report and an Annual Report providing an update on the latest overall safety profile for the investigation should be submitted directly to the MHRA via the MORE portal.

When providing these summaries, use the Quarterly Summary Reports template. This template is for devices only but should also be used for device-related reporting on any combined studies. Do not include detail on any Investigational Medicinal Product (IMP) under investigation.

3.5 Funder Reports

Please familiarise yourself with the requirements for providing progress reports to your funder(s). These will most likely be listed in grant award letters/Terms and Conditions and Funder Contracts.

4.0 Non-compliance

Failure to submit the relevant progress report may result in the Non-Compliance SOP S-1016 UoL being implemented, with action being taken at a Critical level.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Research Governance Office/Infonetica	Send email reminders prior to the submission deadline
Chief Investigator	Chief Investigator (or their delegate)	Complete the relevant progress report form(s) and submit to the applicable regulatory authorities
Chief Investigator	Chief Investigator (or their delegate)	CTIMPs/Medical Device Trials only: Submit appropriate progress report to the Sponsor for review and authorisation
Sponsor	Head of Research	CTIMPs/Medical Device Trials only: Authorise submission to relevant regulatory authorities

Responsibility	Undertaken by	Activity
	Governance (or their delegate)	
Chief Investigator	Chief Investigator (or their delegate)	Submit to relevant regulatory authorities and file signed progress report and all correspondence in TMF

6.0 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 	27/09/2024

7.0 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
July 2024	5.0	Cat Taylor	Revision following national changes to progress reporting requirements across different study types. Updated weblinks added throughout to regulatory body webpages.
September 2024	5.1	Cat Taylor	Revision following further national changes to progress reporting requirements effective as of 1st August 2024. Addition of DSUR REC submission instructions for CTIMPs submitted via the non-combined review route. Minor typographical updates.