




# Research Governance Office Sponsorship Standard Operating Procedures

## Process for Submission of Progress Reports

<b>SOP Reference</b>	S-1022
<b>Version and Date</b>	V5.2 April 2026
<b>Author</b>	
Name	<b>Claire Fitzpatrick</b>
Job Title	<b>Research Quality Assurance Officer</b>
<b>Reviewer/Approver</b>	
Name	<b>Dr Cat Taylor</b>
Job Title	<b>Head of Research Governance</b>
Signature	
Date	<b>28 April 2026</b>
<b>Effective Date*</b>	28 April 2026
<b>Next Review Date</b>	April 2029

SOP Reference	S-1022
Version and Date	V5.2 April 2026
Page Number	Page 1 of 4
Paper copies of this document may not be the most recent version. The definitive version is held on the Research Governance Office <a href="#">SOP webpage</a> .	

## 1.0 Introduction and Scope

This Standard Operating Procedure (SOP) details the procedures for managing the submission of progress reports for research studies (referred to as 'trial' hereafter) sponsored by the University of Leicester (UoL).

## 2.0 Procedure

Progress reporting requirements for a trial are dependent on the regulatory approval(s) received. Where approvals are in place from multiple regulatory bodies, progress reports may be required for all, some, or none of those regulatory bodies. Approximately 30 days prior to the anniversary of REC approval, the RGO will send a generic progress report reminder via email or Infonetica to the CI (or their delegate).

The CI (or delegate) is responsible for ensuring that all required progress reports are completed and submitted within the required timelines to the appropriate review bodies, as detailed in Section 3.0 below. Copies of the submitted report(s) and any supporting correspondence must be filed in the TMF.

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 report template(s).

Progress reports should be submitted annually until the End of Study Declaration form has been submitted.

## 3.0 Reporting Requirements

### 3.1 NHS Research Ethics Committee (REC) Approval

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

### 3.2 University Ethics Approval

For trials 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](#).

**Note:** Evidence of suitable security arrangements must be in place before any support can come into effect. This **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.

SOP Reference	S-1022
Version and Date	V5.2 April 2026
Page Number	Page 2 of 4
Paper copies of this document may not be the most recent version. The definitive version is held on the Research Governance Office <a href="#">SOP webpage</a> .	

### 3.4 Clinical Trials of Investigational Medicinal Products (CTIMPs)

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).

In addition, the HRA Safety and progress reports for CTIMPs procedural [table](#) can also be consulted.

For CTIMPs, the CI (or delegate) must submit relevant progress report form(s) to [rgosponsor@le.ac.uk](mailto:rgosponsor@le.ac.uk) for review and approval prior to submission.

#### 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 may advise the study team to submit a substantial modification.

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.

SOP Reference	S-1022
Version and Date	V5.2 April 2026
Page Number	Page 3 of 4
Paper copies of this document may not be the most recent version. The definitive version is held on the Research Governance Office <a href="#">SOP webpage</a> .	

### 3.5 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).

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.

For medical device trials, the CI (or delegate) must submit relevant progress report form(s) to [rgosponsor@le.ac.uk](mailto:rgosponsor@le.ac.uk) for review and approval prior to submission.

### 3.6 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 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	5.2	<ul style="list-style-type: none"><li>• Formatting changes</li><li>• Updates top wording to align with Clinical Trial Regulations 2025 terminology changes</li><li>• Changes to the procedures section to reflect updated practices and avoid repetition of information contained within other, signposted, SOPs.</li><li>• Removal of responsibilities table as responsibilities are laid out within the body of the SOP.</li><li>• Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive.</li></ul>

SOP Reference	S-1022
Version and Date	V5.2 April 2026
Page Number	Page 4 of 4
Paper copies of this document may not be the most recent version. The definitive version is held on the Research Governance Office <a href="#">SOP webpage</a> .	