St George's University Hospitals NHS
NHS Foundation Trust

St George's University of London

Standard Operating Procedure (SOP)

SOP ID number:	JREOSOP0043	**Effective Date:**	2/01/2018
Version number and date:	Version 3.0 19/12/2017	**Review Date:**	2/01/2020
Author:	Debs Rolfe	**Title:**	Regulatory Assurance Manager
Approved by:	Subhir Bedi	**Date:**	22/12/17
Signature of Authorisor			

This is a controlled document.
The master document is posted on the JREO website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JREO website for the most recent version.
They may print off this document for training and reference purposes.

Standard Operating Procedure (SOP)

Annual Progress Reports

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
v1.0	Original Version	Kirsti Suomi
V2.0	Review of version 1.0. Updated Logo and Trust Name	Anika Kadchha
V3.0	Updated new HRA web links and JREO process	Debs Rolfe

1. Background

NHS Research Ethics Committees (RECs) are required to monitor research that has received a favourable opinion. A progress report should be submitted to the REC which gave the favourable opinion on the anniversary of the date on which the favourable opinion was given. Annual progress reports should be submitted annually thereafter until the end of the study has been declared. An electronic copy should be emailed to the REC within 30 days of each anniversary

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP will describe the process for the preparation, and submission of Annual Progress Reports for any research studies sponsored by St George's.

4. Definitions

For general research management related acronyms used in this SOP refer to "General Research Definitions" working practice document JREOWPD0020

5 Responsibilities

This SOP is to be followed by the JREO Governance section and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance and Delivery (HRGD) to ensure that this SOP is updated by the review date or as necessary.

It is the responsibility of the CI to ensure that they have read and understood the JREO SOPs and ensured that their team familiarise themselves with the SOPs. It is also their responsibility to ensure that they check that they are working with the most current version of the SOPs

The CI is responsible for providing a copy of the Annual Progress Report (APR) and a copy of the REC acknowledgement upon receipt to their named Research Governance and Facilitation Officer (RGFO) or in the case of St George's sponsored CTIMPs, the Regulatory Support Officer (RSO). The CI must also ensure a copy of the APR is filed in the TMF

The RGFO/RSO will acknowledge the APR and make a note on EDGE.
The RGFO will ensure a copy of the APR is filed appropriately in the electronic study folder.
For CTIMPs the RSO will ensure a copy of the APR and subsequent REC acknowledgement is retained in both the appropriate sub-folder of the e-SSF and the physical JREO Sponsor file section 6

6 Procedure

6.1 The First Annual Progress Report

The first annual progress report should be submitted to the REC 12 months after the date on which the favourable opinion was given within 30 days of the reporting period.

The CI is advised to visit the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/ to complete the correct form for submission (dependent on study type)

The CI is also advised to visit the HRA website to ensure REC identification and contact details of original approving committee are current https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/.

The APR should state the commencement date for the study. This is normally assumed to be the date that the study was opened to recruitment by the Sponsor or R&D confirmation of Capacity and Capability was issued at the lead site.

If the study has not started within 12 months of the favourable opinion, an explanation for the delay in the first progress report must be given.

6.2 Annual Progress Reports

Progress reports should be submitted annually thereafter until the end of the study has been declared.

The REC may exceptionally request more frequent reports.

Alternatively, following receipt of the first progress report, the chair of the REC has the discretion to waive the requirement for further reports on receipt of a written request from the Chief Investigator. This might be appropriate where a study has completed recruitment and intervention but has a long period of follow-up with minimal participant involvement. Ensure a copy of this waiver is forwarded to the relevant JREO governance team to facilitate update of the EDGE database and removal of any future APR calendar reminders.

6.3 Review by the REC

The REC office will acknowledge receipt of all progress reports. The CI and/or JREO must file the REC acknowledgement in the Investigator site folder

The REC chair and/or another REC member will normally review progress reports in correspondence. They will notify the full committee at its next meeting that the report has been received.

The Chief Investigator may be invited to attend a meeting of the REC or a sub-committee to discuss the progress of the research.

The REC does not need to re-confirm its favourable ethical opinion each time a progress report is received. It is generally assumed that the opinion applies for the duration of the research, although the REC may review its opinion at any time.

6.4 Multi-Site Studies

In the case of multi-site studies, only one progress report needs to be submitted to the REC. This should be completed by the Chief Investigator. Once REC has acknowledged the APR, the CI is responsible for forwarding this report on to all other participating site R&D teams and their respective PI teams.

6.5 Extension of the period of the study

If the Chief Investigator plans to extend the duration of the study beyond the period specified in the application form, the REC & JREO should be notified in writing, giving reasons for the extra time needed to complete the research. This may include evidence of ongoing costs.

Extension of the study period is not in itself a substantial amendment, except where it is related to other amendments that would be substantial. The CI does not need to obtain a favourable ethical opinion from the REC for extension of the study period.

The RGFO will update the study end date on EDGE and inform the NIHR where relevant.

Extension to a portfolio adopted study may trigger enquiries regarding cover of associated costs – a written agreement from the funder and / or assurances from the Sponsor may be required. Ensure all correspondence is filed in the Investigator study e-folder

6.6 Other Stakeholders

Copies of the APR must be sent to the Sponsor, the PIs at all sites and the R&D offices of all active sites. This allows them to know that the study is still active and is often a condition of Trust approval.

7 References

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/

8 Appendices

None associated with this SOP