St George's University Hospitals NHS
NHS Foundation Trust

# Standard Operating Procedure (SOP)

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| **Signature of Authorisor** | | | |

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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 | | |
|---|---|---|
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| v1.0 | Original Version | Kirsti Suomi |
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## 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 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted annually thereafter until the end of the study. An electronic copy should be emailed to the REC within 30 days of the end of the reporting period.

## 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 (SGHT). 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 both CTIMP and non-CTIMP trials sponsored by both St George's.

## 4. Definitions

**4.1 REC** - the Research Ethics Committee (REC) which gave the favourable opinion

## 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 (HRG) to ensure that this SOP is updated by the review date or as necessary.


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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 the Research Governance Officer (RGO). The CI must also ensure a copy of the APR is filed in the TMF

The RGO will acknowledge the APR and make a note on ReDA stopping any related reminder email alerts. The RGO will ensure a copy of the APR is filed in the electronic study folder located within the Governance folders of the investigators folders on the shared drive: W:\Investigators. The RGO will check ReDA and update the next APR alert date, ensuring correct recipients are included.

# 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.

The CI is advised to visit the HRA website to ensure they have the correct email contact and the correct address location of the REC that originally approved the study.

The APR should state the commencement date for the study. This is normally assumed to be the date on which any of the procedures in the protocol are initiated.

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.

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


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involvement. Ensure a copy of this waiver is forwarded to the JREO governance team to facilitate update of the ReDA database and removal of any future APR email alerts.

### 6.3 Review by the REC

The REC office will acknowledge receipt of all progress reports.

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 will usually be done by the Chief Investigator. Once REC has acknowledged the APR, the CI is responsible for forwarding this report on to all other participating sites.

### 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.

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 RGO will update the study end date in ReDA Project Information and email alerts within ReDA, along with ensuring all email recipient details are also current and up to date.

### 6.6 Other Stakeholders


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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

Annual Progress Report Forms
www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/

## 8. Appendices

None associated with this SOP


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