Standard Operating Procedure (SOP)

Annual Safety Reporting and Annual Progress Reporting for Research Sponsored by St George's

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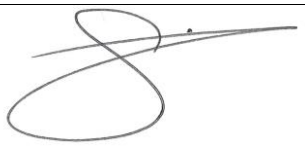
Author:	Georgia Bullock	**Title:**	Research Development and Governance Manager
Approved by:	Subhir Bedi	**Date:**	21/06/2021
Signature of Authoriser			

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

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

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Subhir Bedi
V2.0	Updated to new JREO SOP template and DSUR reports replacing ASRs	Debbie Rolfe
V3.0	Updated Trust status & logo, updated emails and external links	Debs Rolfe
V4.0	Updated with electronic submission format via CESP	Debs Rolfe
V5.0	**Update to incorporate JREOSOP0043 into this SOP.** Change of JREO to JRES and minor amendments to text in all sections. Update to Associated JRES documents table. Updated references/links to relevant websites.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions	JRESDOC0003 TMF Index JRESDOC0004 ISF Index JRESDOC0046 DSUR Template	

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1. Background

The MHRA and NHS Research Ethics Committees (RECs) require annual updates on how research is progressing, including an update on safety information for CTIMPs. There are two annual reports that have to be submitted:

- A Development Safety Update Report (DSUR)
- An Annual Progress Report (APR)

The DSUR:

- is only required for CTIMPs.
- collates all relevant new safety information for the reporting period, to ensure the ongoing safety of the participants.
- must be sent to the MHRA as per their reporting procedure, and a copy sent to the main REC as per their reporting procedure.
- must be submitted initially **1 year after the first CTA approval** for the trial and every year after this until the **last visit of the last patient** in the member state concerned.
- can be submitted up to 60 days before or up to 60 days after the CTA approval date.

The APR:

- must be submitted to the REC which gave the favourable opinion, for all types of approved research including CTIMPs, as per their reporting procedure.
- must be submitted initially **12 months** after the date on which the favourable opinion was given and every year after this until the end of the study.
- can be submitted up to 60 days before or up to 30 days after the REC favourable opinion anniversary date.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES 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 describes the process for the preparation and submission of DSURs and Annual Progress Reports for any research studies which are sponsored by St George's.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

This SOP is to be followed by the JRES Governance team and the Chief Investigator (CI) of the study.

6. Procedure

6.1 DSUR

a) The CI must:

- Complete the DSUR using the JRES template (JRESDOC0046).
- Review any previous reports to provide updated information on anything included in these.
- Include a line listing of all suspected serious adverse reactions (including all SUSARs) that occurred in the trial. Full details of what needs to be included can be found on the MHRA website MHRA DSURs.
- Submit the completed report to the JRES and respond to any queries raised by the JRES in a timely manner.
- Sign the final approved DSUR and return it to the JRES.

b) The Clinical Research Associate (CRA) at the JRES must:

- Send email reminders to the study team and CI for the preparation of the DSUR (within 60 days of the submission date). The DSUR workflow on EDGE should be completed which will update the reminders within PowerBI (PowerBI should be reviewed periodically to see which reports are due).
- Liaise closely with the relevant CI regarding the DSUR completion and acknowledge receipt of the completed DSUR when received.
- Review the DSUR to check for completeness and accuracy (including all SAEs/SUSARs) and send any queries to the CI.

- Produce a PDF version of the completed DSUR once finalised and send it to the CI for signing.
- Save the signed PDF to the electronic Sponsor file and update the Workflow on EDGE.
- Submit the PDF of the signed DSUR to the MHRA via the MHRA Submissions Portal. The MHRA does not acknowledge receipt of the DSUR. The submission details should be used as evidence of the DSUR submission for the TMF.
- Submit a copy of the DSUR to the main REC for the trial by email. The report must be accompanied by a CTIMPs Safety Report Form which can be found on the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/ The REC will acknowledge receipt of the report within 30 days.
- Ensure that a copy of the DSUR is sent out to all participating sites.
- File all documentation and correspondence in the relevant Sponsor files and ensure that all documentation/correspondence is filed in the TMF.

6.2 APR

a) The CI must:

- Follow the guidance on the HRA website to ensure the correct form is submitted for the APR (dependent on the type of study): https://www.hra.nhs.uk/approvals- amendments/managing-your-approval/progress-reports/
- Ensure that the APR states 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 the date that the confirmation of Capacity and Capability was issued at the lead site.
- Ensure an explanation is provided for any study which has not started within 12 months of the favourable REC opinion.
- Sign the completed report.
- Email a signed electronic copy to the correct REC within 30 days of the end of the reporting period.
- Provide a copy of the APR and REC acknowledgement to their JRES contact.
- File the APR and acknowledgment in the TMF.

b) The JRES must:

- Acknowledge receipt of the APR and update EDGE and the Sponsor files.

In the case of multi-site studies, only one progress report needs to be submitted to the REC. This should be completed by the CI. Once the REC has acknowledged the APR, the CI is responsible for forwarding this report on to all R&D offices for active sites and their respective PI teams. The site team should file the APR in the ISF.

Where the CI fails to submit the APR within three months of the due date, the REC will notify both the CI and the Sponsor. Multiple instances of non-compliance could lead to suspension or termination of the trial.

7. References

DSUR:

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

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

APR:

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

8. Appendices

None associated with this SOP.