Standard Operating Procedure (SOP)

End of the Study Notification

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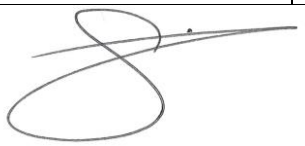
Signature of Authoriser			

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They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	New SOP	Zuhur Balayah
V2.0	Review of V1.0 (Original Version).	Ira Jakupovic
3.0	Update to new JREO ref and procedures. Addition of non CTIMP studies	Lucy H Parker
4.0	New Logo and Trust name and change of title to Head of Research Governance	Lucy H Parker
V5.0	Review and updated SOP format	Debs Rolfe

V6.0	Reflecting changes in JREO to JRES and job titles and minor changes to delegations of responsibilities. Insertion of Associated JRES documents. Update to procedure for the final report as per MHRA guidance.	Ali Alshukry / Georgia Bullock

Associated JRES documents

SOPs/Policies	WPDs	Docs	LOGs
JRESGOVSOP0011 Management of Amendments StG Sponsored JRESGOVPOL0001 Clinical Trial Transparency Policy JRESGOVSOP0016 Archiving	JRESWPD0023 General Research Definitions		

Contents

1. Background

The Clinical Trials Regulations and the Research Ethics Service (RES) state that for all Clinical Trials of Investigational Medicinal Products (CTIMPs) and for all other research (non-CTIMPs), written notification of the end of study should be submitted within 90 days of the end of project, or within 15 days if the project is terminated early. The end of study declaration should also be followed up with a report of the study findings within 12 months of declaring the end of the study to the REC (6 months for paediatric trials).

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 procedure to be followed by the JRES and the CI to declare the end of a study to the REC and if a CTIMP, the MHRA.

This SOP only applies to those studies sponsored by St George's University of London (SGUL) and/or St George's University Hospitals NHS Foundation Trust (SGHFT).

4. Definitions

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

5. Responsibilities

The CI must ensure that:

- The End of the Trial (EOT) is clearly defined in the protocol. This is normally Last Patient, Last Visit "LPLV"; if this changes, it is a substantial amendment and the SOP on amendments (JRESGOVSOP0011) must be followed.

- The End of Trial Notification Form is completed and submitted to the REC, the MHRA (if applicable) and to the JRES in accordance with this SOP and regulatory requirements.

- Acknowledgment of the EOT form is received from the REC and the MHRA (if applicable) and passed onto the JRES.

- For multi-site studies, all participating sites and site personnel (including pharmacy) will be notified of the trial end.

- The final study report is written and submitted to the JRES, the REC and notification provided to the MHRA (if applicable) that the report has been uploaded onto the relevant trial register in accordance with this SOP.

6. Procedure

The Declaration of the End of Trial Form must be submitted to the REC and the MHRA (if applicable) **within 90 days** of the End of the Trial, or **within 15 days** if the study is terminated early (specifying any reasons for early termination).

The forms for both CTIMPs and other research can be found on the HRA website: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

6.1 Process for CTIMPs

If a CTIMP, the Form should be completed when:

a. the trial ends in the United Kingdom (UK)
   and/or
b. The complete trial has ended in all participating centres in all countries both within and outside the EU.

The form should be completed by the CI or their delegate and sent to the REC that approved the study. The CI or delegate will need to visit the HRA website to check the latest REC contact details

of the original REC that approved the study or that has now taken on that responsibility. The form should also be sent to the JRES in their remit as Sponsor, as well as to any site at which the study was active.

The JRES named Sponsor contact must also send the completed form to the MHRA.

The CI or delegate must ensure that the REC acknowledges the receipt of the form. If the REC has not acknowledged the receipt of the form within 35 days, the CI or delegate should contact them and enquire about the acknowledgement letter. A copy of this letter must be sent to the JRES.

Once the JRES has received a copy of the form, they will ensure that the End of Trial date, the date of the acknowledgement letter and the Final Report date are recorded on the JRES databases and that the assigned Clinical Research Associate (CRA) and Research Development and Governance Manager (RDGM) are informed. This will allow the CRA to arrange a close-out visit (if applicable).

The CRA/RDGM will change the study status to closed on the JRES EDGE database which will set up a reminder on PowerBI to ensure a Final Study report is submitted within the 1-year anniversary date of EOT declaration. For paediatric trials, results should be made public within 6 months of the EOT declaration.

6.2 Process for non-CTIMPs

The CI or delegate should complete the appropriate form and send it to the REC which gave a favourable opinion of the research. The form should also be sent to the JRES in their remit as Sponsor as well as to any site at which the study was active.

Once the JRES has received a copy of the form, they will ensure that the End of Trial date, the date of the REC acknowledgement letter and the Final Report date are recorded on the JRES database.

6.3 Process for declaring a temporary halt of the study

If the study is suspended or halted temporarily (eg: by the Sponsor due to a persistent non-compliance), the CI or delegate must complete a substantial amendment form and clearly explain the reasons for the halt. This must be done within **15 days** of the suspension. The JRES SOP on Management of Amendments must be followed (JRESGOVSOP0011).

6.4 Process if the study does not start

If the CI decides not to commence a trial, they should notify the MHRA (if applicable), REC and Sponsor and clearly explain the reasons for not starting the trial. This should be done using the relevant end of study declaration form from the HRA website. The JRES database and the electronic Investigator File must be updated.

6.5 Final report of the trial

The CI should produce a summary of the final trial report. If this report was not enclosed with the End of Trial declaration, it will need to be sent subsequently and within 12 months of declaring the end of the study.

As a minimum, the final report should state whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

Guidance on who to submit the final report to, and how to do this, can be found here:
Ending your project - Health Research Authority (hra.nhs.uk)
The JRES should also be provided with a copy of the report.

For CTIMPs, it is a legal requirement to make all trial results available on the public register(s) where the trial was originally registered, within 12 months of the end of the trial. The JRES requires that St George's sponsored CTIMPs use the ISRCTN register as a minimum. Please see JRESGOVPOL0001 Clinical Trials Transparency Policy for further guidance.

The upload of the final study report and results to the public register is the responsibility of the Sponsor with input from the CI as required.

6.6 Archiving

Archiving arrangements for study-related documents should follow the procedures described in the SOP for Archiving (JRESGOVSOP0016).

7. References

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#end-of-trial

8. Appendices

None associated with this SOP.