St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure

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Approved by:	Debs Rolfe	**Date:**	30/10/2015
Signature of Authorisor			

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

Standard Operating Procedure (SOP)
Notification of the End of the Study

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 H Parker
4.0	New Logo and Trust name and change of title to Head of Research Governance	Lucy H H Parker

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1. Background

The Medicines for Human Use (Clinical Trial) Regulations (2004) and the National Research Ethics Service (NRES) 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 notified 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 and to the MHRA (if applicable)

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. 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 Sponsor (JREO) and the Chief Investigator (CI) to declare the end of a study to the Research Ethics Committee (REC) and if a CTIMP, the Medicines and Healthcare products Regulatory Agency (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 (SGHT).

4. Definitions

Not applicable to this SOP

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5. Responsibilities

The CI must ensure:

- 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 (JREOSOP0011) must be followed.

- The End of Trial Notification Form (hereafter referred to as the Form) is completed and submitted to the REC, the MHRA (if applicable) and to the JREO in accordance with this SOP and the Competent Authorities guidelines;

- The Form acknowledgement is received from the REC and the MHRA (if applicable)and passed onto the JREO;

- If multi-centred, all sites participating and site personnel (including pharmacy) are notified of the trial end;

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

6. Procedure

The 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).

6.1 Process for declaring the end of a CTIMP Study

If a CTIMP, the Form should be completed when:

a. the trial ends in the United Kingdom (UK)

   and/or

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b. The complete trial has ended in all participating centres in all countries within and outside the EU.

The Form (Appendix One) should be completed by the CI and sent to the REC that approved the study. The CI 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. This Form is available on the JREO website as a Word version. The Form should also be send to the JREO in their remit as Sponsor as well as to any site at which that the study was active.

The JREO named Sponsor contact must also send the completed Form to the MHRA in accordance with JREOWPD0004 MHRA submission format

The CI 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 should contact them and enquire about the acknowledgement letter. A copy of this letter must be sent to the JREO.

Once the JREO 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 JREO databases and that the CTM and RAM are informed. This will allow the assigned CTM to arrange a close out visit (JREOSOP0014)

The CTM/RAM will change the study status to closed on ReDA and set up an email alert/reminder in ReDA to ensure a Final Study report is submitted within the 1 year anniversary date of EOT declaration

6.2 Process for declaring the end of a non CTIMP Study

The CI should complete the appropriate form (Appendix Two) and send it to the REC which gave a favourable opinion of the research. This Form is available on the JREO website as a Word version. The Form should also be send to the JREO in their remit as Sponsor as well as to any site at which the study was active.

Once the JREO 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 ReDA database

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The RGT upon receipt of the End of Trial Declaration letter will change the study status to archived on ReDA.

6.3 Process for Declaring a Temporary Halt of the Study

If the study is suspended or halted temporarily (*e.g.* by the Sponsor due to a persistent non-compliance, for example), the CI must complete a substantial amendment form and explain clearly the reasons for the halt. This must be done within 15 days of the suspension. The JREO SOP on substantial amendments must be followed (JREOSOP0011).

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. ReDA should be amended and the electronic Investigator File.

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.

There is no standard format for final reports. As a minimum, the chief investigator should inform the REC and the JREO whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants. For CTIMP studies the study report will need to be uploaded onto the EudraCT database – proof will be required to facilitate informing the MHRA.

St George's encourage all investigators to ensure their trial results are made publicly available. A copy of the final report should be uploaded onto the database hosting the trial record in accordance with JREOSOP0022

6.6 Archiving

Archiving arrangements for study related documents are described in the SOP for Archiving arrangements JREOSOP0016 and should be followed.

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7. References

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031, implemented 1st May 2004, and as amended thereafter)

www.hra.nhs.uk/resources/during-and-after-your-study/

JREO SOP Management of amendments (JREOSOP0011)

JREO SOP Archiving (JREOSOP0016)

JREO SOP Monitoring Close out visits (JREOSOP0014)

JREO SOP Publicly accessible databases (JREOSOP0022)

8. Appendices

Appendix 8.1: End of Study Declaration – CTIMP study

Appendix 8.2: End of Study Declaration – non CTIMP study

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Appendix 8.1: End of Study Declaration – CTIMP study

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number : (..) **B.2 Sponsor's protocol code number: (..)** **B.3 Full title of the trial :**

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☐
C.1.2	Legal representative of the Sponsor	☐
C.1.3	Person or organisation authorised by the Sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation :	
C.1.4.2	Name of person to contact :	
C.1.4.3	Address :	
C.1.4.4	Telephone number :	
C.1.4.5	Fax number :	
C.1.4.6	E-mail	

[1] OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

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C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the Sponsor	☐
C.2.3	Person or organisation authorised by the Sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
•	Co-ordinating investigator (for multicentre trial):	☐
•	Principal investigator (for single centre trial):	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation:	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial**?
D.1.1	(YYYY/MM/DD):

D.2	**Is it an early termination?**[3]	yes ☐ no ☐
D.2.1	If yes, give date (YYYY/MM/DD):	
D.2.2	Briefly describe in an annex (free text):	
D.2.2.1	The justification for early termination of the trial;	
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;	
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1	I hereby confirm that/confirm on behalf of the Sponsor that (delete which is not applicable): • The above information given on this declaration is correct; and • That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]	
E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☐
E.2.1	Date :	
E.2.2	Signature :	
E.2.3	Print name:	
E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name:	

[2] According to national legislation.
[3] Cf. Section 4.2. of the detailed guidance CT-1.
[4] Section 4.3. of the detailed guidance CT-1.

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Appendix 8.2: End of Study Declaration – Non CTIMP

NHS
Health Research Authority

DECLARATION OF THE END OF A STUDY

(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC") within 90 days of the conclusion of the study or within 15 days of early termination. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Research Sponsor:	

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Name of main REC:	
Main REC reference number:	

3. Study duration

Date study commenced:	
Date study ended:	
Did this study terminate prematurely?	*Yes / No* *If yes please complete sections 4, 5 & 6, if no please go direct to section 7.*

4. Circumstances of early termination

What is the justification for this early termination?	

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5. Temporary halt

Is this a temporary halt to the study?	*Yes / No*
If yes, what is the justification for temporarily halting the study? When do you expect the study to re-start?	*e.g. Safety, difficulties recruiting participants, trial has not commenced, other reasons.*

6. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.	

7. Final report on the research

Is a summary of the final report on the research enclosed with this form?	*Yes / No* *If no, please forward within 12 months of the end of the study.*

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8. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

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