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Approved by:	Lucy H H Parker	**Date:**	14/09/15
Signature of Authorisor			

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Standard Operating Procedure (SOP)

Sponsor cover for Adverse Events Reporting for St Georges Sponsored studies during University Closure

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1	New SOP to describe arrangements for SAE reporting during University closure at Christmas	Debs Rolfe
V2	Update Trust logo and status. Updated JREO email, updated Appendix SAE reporting form	Debs Rolfe

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1. Background

The European Clinical Trials Directive (EUCTD) 2001/20/EC was transposed into UK Regulations by The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) on 1st May 2004. 'UK Regulations' will be the term used to cover the UK legislation and the EUCTD in this document. The UK Regulations [and its subsequent amendments] set out the legal requirements for Adverse Event (AE) recording, management and reporting in clinical trials. These regulations apply to all Clinical Trials of Investigational Medicinal Products (CTIMPs) and specify 'Pharmacovigilance (PCV)' reporting requirements. To breach these requirements constitutes a breach in criminal law. The requirements have been incorporated into this Standard Operating Procedure (SOP) to define procedure undertaken by the Sponsor (St George's University of London (SGUL) and/or St George's University Hospitals NHS Foundation Trust (SGHT) to comply with the UK Regulations.

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 describes the procedure for the Research Pharmacy Staff to ensure continuity of sponsor oversight of SUSAR reporting during prolonged University closure, specifically closure over Christmas and New Year.

This SOP is to be used by the Research Pharmacy following receipt of a notification of a Serious Adverse Events (SAE) or Suspected Unexpected Serious Adverse Reactions (SUSARs) that require reporting in accordance with the UK Regulation and that occur in participants participating in CTIMPs sponsored by St George's. It also provides details of the responsibilities of the Investigator (Section 5).

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4. Definitions

4.1 Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)

Any untoward medical occurrence that at any dose : results in death, is life-threatening, requires inpatient hospitalisation or prolongation of hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly or birth defect

NB: hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Therefore participants do not need to be hospitalised overnight to meet the hospitalisation criteria.

Hospitalisation for an elective procedure or for a pre-existing (prior to study entry) condition which has not worsened is not defined as an SAE

4.2 Unexpected Adverse Reaction (UAR)

An adverse reaction, the nature or severity of which is not consistent with the applicable reference safety information. (SmPC or IB)

4.3 Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction that is classed in nature as both serious and unexpected

5. Responsibilities

5.1 Investigator Responsibilities for the benefit of the Research Pharmacy

a) It is the responsibility of the CI and the individual investigators within the research team to follow the JREOSOP0006 Reporting of Adverse Events for CTIMPs sponsored by St George's and keep records of all AEs that occur in trial participants in accordance with the protocol

5.2 The Research Pharmacy (RP) responsibilities during University Closure

a) The RP will ensure acknowledgement of receipt of SAE recording forms is communicated via email to both the reporter and the Chief Investigator within 2 working days copying the email to adverseevents@sgul.ac.uk

b) The RP will assess the SAE recording form and will escalate any unexpected fatal SAEs or a SUSAR to the MHRA within 7 days of receipt

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c) Upon receipt of an SAE recording form for a fatal SAE or a SUSAR, the RP will immediately assess the form for accuracy and completeness and respond with any queries or points for clarification to the study team within 5 working days of receipt

d) The RP will submit an initial report for any notified SUSARs electronically to the MHRA

e) The RP will forward a copy of the saved electronic SUSAR report file to the Chief Investigator and copy the email to adverseevents@sgul.ac.uk to facilitate notification/escalation to all other site investigators

6. Procedure

6.1 Investigator Procedure(for the benefit of the RP)

a) The Investigator must follow JREOSOP0006

6.2 JREO Procedure

a) Ensure that prior to University closure that switchboard is contacted to request that the JREO fax number is redirected to the Research Pharmacy fax number 0208 725 4167

b) The Regulatory Assurance Manager (RAM) or Clinical Trials Monitor (CTM) will give the RP a courtesy phone call on ex 1294 to inform the lead Research Pharmacist that the JREO fax number has been redirected.

c) A test fax should be sent from either the JREO or pharmacy fax to ex 0794 to check redirection is working.

d) Upon re-opening of the University after the Christmas/New Year closure, the RAM/CTM will contact the switchboard to request that the ex 0794 divert is cancelled

e) The RAM/CTM will contact the RP to obtain any paperwork and updates on any actions performed during the university closure

f) The RAM/CTM will forward any reported SUSARs to the relevant ethics committee when the University is reopened.

g) The RAM/CTM will submit any follow up information for reported SUSARs as required to the MHRA

h) The RAM/CTM will process any remaining SAEs as in 6.3 (c) below by following JREOSOP0006

i) The RAM/CTM must ensure the adverseevents@sgul.ac.uk is checked and each email is acknowledged, appropriately actioned and followed up. Upon resolution the email communication trail should be saved electronically in the individual Investigator electronic study file.

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6.3 Research Pharmacy procedure

The RP will check the Research Pharmacy fax on a working daily basis for study SAEs report forms

a) Check the SAE form to assess if the reported event is either **a fatal SAE** or has been assessed as a SUSAR by checking the expectedness and relatedness fields – **Act only** if event has been marked as **unexpected** and causality assessed **as likely/possible/probable or unassessable**

b) If **not** fatal or **not** a SUSAR then simply acknowledge receipt as in (d) and sign/date form as in (i)

c) Ensure all fields are complete, make sense for example dates in relation to other recorded dates on the form and that the Chief Investigator has been informed

d) Ackowledge the receipt of the SAE form by email to the sender ensuring the Chief Investigator, study co-ordinator and that adverseevents@sgul.ac.uk are copied in – this may be the opportunity to address any initial queries or clarifications required from point (c) above.

e) **If the Investigator has assessed the event as unexpected and the causality has been assessed as definite, possible, probable or not assessable then report as a SUSAR go to point (f) below–** The event can always be downgraded to an SAE at a later date if reassessed as not fulfilling the SUSAR definition

f) Log onto the MHRA website at the following link https://esusar.mhra.gov.uk/ and follow the instructions

g) Save the MHRA submitted form into an electronic file and forward to the Chief Investigator (copy to adverseevents@sgul.ac.uk)

h) Complete, sign and date the JREO review box (last page) of SAE reporting form and retain original to pass to the JREO for inclusion in the handover upon the re-opening of the University

i) Any follow up information to the SUSAR must be submitted (if/when received) to the MHRA via the link in (f) above within the reporting timelines. Any fatal or life threatening SUSARs must be reported within 24 hours of first knowledge and follow up reports must be sent no later than 8 days after the initial report. Any non-fatal or non-life threatening SUSARs must initially be reported within 15 days (although the likelihood will be that the university will have reopened before this is necesary*)*

7. References

https://esusar.mhra.gov.uk

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8. Appendices

Appendix 8.1 :JREODOC0012 SAE Reporting form

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Appendix 8.1

SERIOUS ADVERSE EVENT REPORTING FORM

Fax to 020 8725 0794 or email adverseevents@sgul.ac.uk within 1 working day of identification of event

Section A: Study Information Initial Report ☐ or Follow up ☐ number..... ? ☐

STUDY ID:	EudraCT ID	
JREO:	Chief Investigator	Study Site PI:
Sponsor : SGH or SGUL	Rec Reference	

Section B: Patient information

Patient Initials:	Patients Trial/study ID:	
Patient DOB:	Patient Gender M or F	Study arm/Cycle Number
Reporting Site ID:		

Section C: Details of SAE event

Main event or symptom in 1st row followed by any associated symptoms. One MAIN event per form – if two events use two forms	Severity/Intensity Mild/moderate/severe	Date of Onset dd/mm/yy approx. time of onset if available	SAE status 1 = resolved 2= Resolved with sequelae 3= on-going 4= worsened 5 = fatal	Date Resolved dd/mm/yy
Associated Symptoms				

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Why was Event Serious? 1 = Resulted in death 2 = Life threatening 3 = Required in-patient hospitalisation or prolongation of existing hospitalisation 4 = Persistent or significant disability/incapacity 5 = Congenital anomaly/defect 6 = Other important medical condition please specify.....		Where did the SAE take place? 1 = Hospital 2 = Out-patient Clinic 3 = Home 4 = Nursing home 5 = Other, specify.....		
Date PI or site was notified or became aware of SAE				

Section D: IMP or Study drug information

Trial drug Frequency and dose as per protocol	Date of 1st administration dd/mm/yy	Date of most recent administration dd/mm/yy	Actual dose given at most recent administration Provide with units and frequency	Route 1 = oral 2 = Intravenous 3= Subcutaneous 4= Intramuscular 5 = other – specify	Causal relationship to SAE 1 = Definitely 2 = Probably 3= Possibly 4 = Unlikely 5 = Not related 6 = Not assessable	Expectedness Was the event one of the recognised undesirable effects of trial medication 1 = expected 2 = unexpected	Action taken due to SAE 1 = None 2= dose reduction 3 = Treatment delayed 4 = Treatment reduced and delayed 5 = Treatment stopped 6 = Code Break (blinded studies only)

Describe Serious adverse event (include manifestation & progression of event any treatments given to any response to the event, including dose and route, and any relevant tests carried out- continue on a separate sheet if necessary)

Diagnostic tests : Please attach reports Number of reports attached

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Test Name					
Date					
Normal range					
Result (+ units)					

Section E: Concomitant medication

Concomitant Treatment taken at time of the event/Medication taken to treat event (generic name)	Total Daily Dose	Route 1 = oral 2 = Intravenous 3= Subcutaneous 4= Intramuscular 5 = other – specify	Indication for prescription	Start Date dd/mm/yy	Ongoing 1 = yes 2 = No	End date dd/mm/yy

Do you consider this event likely to have been caused by anything other than the treatments listed previously on this form

1= yes 2 = No

If yes specify : including medical history, drug or alcohol abuse, family history or findings from special investigation

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Section F: CI or PI information (Signed on delegation log)

Reporting Site Personnel details Name:	Contact details
Signed by Clinician (Responsible person) Print Name :	Contact Number : Date of Completion :

Section G: JREO

JREO Review	Date Checked by Reviewer
SAE ☐ SAR ☐ SUSAR: 7 DAY ☐ SUSAR 15 DAY ☐	SAE Number nb- Enter on PV database
Code Break Requested (for blinded studies Only) by whom:	Date Code break performed: NB- CONSULT PROTOCOL TO CONFIRM WHOM TREATMENT ALLOCATION CAN BE REVEALED TO – DO NOT ATTACH TO THIS REPORT IF COPY RETURNED TO TMF
If SUSAR – Date reported to MHRA	Name & Signature of JREO RGT member :
CI Informed: Y/N	Date CI informed:

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