SOP ID number:	JREOSOP0041	**Effective Date:**	04/01/2018
Version number and date:	Version 3 19/12/2017	**Review Date:**	06/01/2020
Author:	Debs Rolfe	**Title:**	Regulatory Assurance Manager
Approved by:	Subhir Bedi	**Date:**	21/12/2017
Signature of Authorisor			

This is a controlled document.
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)

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
V3.0	Update to new SOP format	Debs Rolfe

Table of Contents	Page
1. Background	3
2. Joint Research and Enterprise Office (JREO) Policy	3
3. Scope	3
4. Definitions	4
5. Responsibilities 1. Investigator Responsibilities for benefit of Research Pharmacy 2 Research Pharmacy Responsibilities during University Closure	 4 4
6. Procedures 1. Investigator Procedure 2 JREO Procedure 3 Research Pharmacy procedure	5 5 5 6
7. References	6
8. Appendices None	

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 (PV)' 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 (SGHFT) 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 (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 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 Regulations 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).

4. Definitions

For general research management related acronyms used in this SOP refer to "General Research Definitions" working practice document JREOWPD0020

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
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 020 8725 4167

b) The Regulatory Assurance Manager (RAM) or Regulatory Support Officer (RSO) 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/RSO will contact the switchboard to request that the ex 0794 divert is cancelled

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

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

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

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

i) The RAM/RSO 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.

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 (h)

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

JREODOC0012 Serious Adverse Event Reporting Form

8. Appendices

None