St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Signature of Authorisor			

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Standard Operating Procedure (SOP)
Safety reporting for Non CTIMP Studies

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V 1.0	Original Version	Praveen Macherla
V 2.0	Updated Logo and Trust Name	Anika Kadchha
V 3.0	Updated definition and added Adverse Incident reporting	Debbie Rolfe

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1. Background

It is essential that all adverse events which occur during the course of study participants' involvement in a research project are appropriately recorded and reported in order to ensure their continuing safety. To ensure the interests and safety of subjects participating in clinical trials, this Standard Operating Procedure must be followed for all research studies that do not fall under the Clinical Trials Directive 2001/20/EC

Studies that involve medical devices, diagnostic products and therapeutic interventions do not fall within the definition of investigational medicinal products (IMPs) in Directive 2001/20/EC and are called non-investigational medicinal products (NIMPs). The Research Governance Framework also lays out the requirement for safety reporting during a study.

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 process for recording, managing safety and reporting Adverse Events or Incidents for St George's sponsored non CTIMP studies or for non-CTIMP studies hosted by St Georges.

This SOP does not cover safety reporting for CTIMPs. Safety reporting for CTIMPs is covered in JREOSOP0006.

4. Definitions

4.1 Adverse Event: An adverse event (AE) is defined as any unfavourable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical intervention or procedure, regardless of whether it is considered related to the medical intervention or procedure, that occurs during the course of the study.

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4.2 Serious Adverse Event: Any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect. Important adverse events/reactions that are not immediately life threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed above should also be considered serious.

4.3 Sponsor

An individual, company, institution or an organisation which takes on the responsibility for the initiation, management, and/or of the financing of a clinical trial.

4.4 Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the **principal investigator (PI)**.

4.5 Chief Investigator (CI)

An investigator assigned the overall responsibility for the trial including the coordination of participating principal investigators at participating sites within a multicentre trial.

4.6 Adverse Incident. An adverse incident are events which effect the health and safety of patients or service users, equipment users or operators, or other persons. An Adverse Incident in relation to a medical device is an event that causes or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. E.g. a patient, user, carer or professional is injured as a result of a medical device failure or its misuse, or if a patient's treatment is interrupted or compromised by a medical device failure, or a misdiagnosis due to a medical device failure which leads to inappropriate treatment or a patient's health deteriorates due to medical device failure. Causes may include: design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

5. Responsibilities

The Chief Investigator (CI) has overall responsibility for the conduct of the study. In a multi-site study, the CI has co-ordinating responsibility for reporting adverse events to the Sponsor and to the relevant Research Ethics Committee (REC).

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The Principal Investigator (PI) has responsibility for the research at a local site where the study involves specified procedures requiring site-specific assessment. There should be one PI for each research site. In the case of a single-site study, the CI and the PI can be the same person. The PI is responsible for informing the CI or the organising research team and JREO, of all adverse events that occur at their site.

6. Procedure

All protocols should list known side effects; adverse reactions contained within the manufacturer's product information or technical specifications and expected events in relation to the disease or population being studied that would not require expedited reporting. A detailed explanation of SAE reporting procedures should also be included in the protocol.

Each AE must be evaluated for **seriousness, causality, and expectedness**. The responsibility for this evaluation can be shared between the CI and PIs. It may be most appropriate for the treating PI at each local site to evaluate whether each event is related and unexpected, before reporting it to the CI and Sponsor simultaneously. SAEs that are reportable are:

☐ '**related**': that is, it resulted from administration of any of the research procedures; and
☐ '**unexpected**': that is, the type of event is not listed in the protocol as an expected occurrence.

The CI can decide how to record and report adverse events, whether expected or not. Adverse events must be recorded in the first instance in the participant medical notes. The Case Report Forms (CRFs) should also include an Adverse Event report where the event should be clearly described. It should be clearly stated in the study protocol and the local SOP what will be recorded and how the onward reporting and the ongoing participant management should be processed. Adverse events that occur during the course of the Research project should be recorded collectively e.g. JREOLOG0007 Adverse Event Log. The log should be maintained and retained in the Investigator Site File. The Sponsor may require regular collection or periodic updates of AE occurrence.

You should also consider whether the event qualifies for reporting through the Trust's incidence system.

The Adverse Incidents Reporting Policy and Procedures can be accessed following this link:

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http://stginet/Units%20and%20Departments/Governance/Risk%20Management/Advers%20Incident%20Reporting/Adverse%20Incident%20Reporting.aspx

If a research participant experiences a SAE the CI should complete the SAE form (Appendix 1) and ensure the JREO is informed. It will be the CI's responsibility to forward the completed form to the relevant Ethics Committee and to the Sponsor via email. The JREO adverse events mailbox should be included – adverseevents@sgul.ac.uk.

Reports of **related** and **unexpected** SAEs should be submitted within 15 days of the CI becoming aware of the event.
The REC will acknowledge receipt of the report within 30 days by signing the SAE form and returning a copy back to the person who made the submission.
This signed copy will need to be retained in the appropriate section of the Investigator Site File.

For Investigational studies that may include a medical device the report must also be made to the device manufacturer in accordance with the protocol

For any deaths that occur during the course of the research project- refer to the protocol which will provide guidance as to when the Sponsor and in some cases the JREO are required to be informed.

7. References

JREOLOG0007 Adverse event log

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

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Appendices

Appendix 1: HRA SAE report form for non CTIMP studies

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Appendix 8.1 REPORT OF SERIOUS ADVERSE EVENT (SAE)
(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Name of main REC:	
Main REC reference number:	

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Research sponsor:	
Sponsor's reference for this report: (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate options:

Death ☐	Life threatening ☐	Hospitalisation or prolongation of existing hospitalization ☐
Persistent or significant disability or incapacity ☐	Congenital anomaly or birth defect ☐	Other ☐

4. Circumstances of event

Date of SAE:	
Location:	
Describe the circumstances of the event: *(Attach copy of detailed report if necessary)*	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

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5. Declaration

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

6. Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back to Chief Investigator (or other person submitting report)
Copy to be kept for information by main REC.

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