St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Signature of Authorisor			

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

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
V4.0	Updated SOP in line with HRA process and new SOP format	Debs Rolfe

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. The UK policy Framework for Health and Social Care Research 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 (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 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

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

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).

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 and when safety reporting for individual participants should commence and end in relation to consent and or study interventions.. 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:

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

For any studies hosted at St Georges the PI must follow the instructions provided by the Sponsor to ensure safety reporting timelines are met.
The PI must retain all correspondence and completed paperwork within the ISF.
All adverse events and/or incidents must be documented in the participant medical records

St George's Sponsored studies - If a research participant experiences a SAE the CI should complete the Non-CTIMP safety report to REC form available - https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/ 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 JREO via email. 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.

JREO governance team that are notified of a Serious Adverse Event via the adverseevents inbox must check that the approving ethics committee and Chief Investigator of the Trial are aware/ in receipt of the report.

File the completed form/email correspondence in the study e-folder in the Reports sub-folder.

7. References

JREOLOG0007 Adverse event log

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/