Standard Operating Procedure (SOP)
Safety Reporting for Non-CTIMPs

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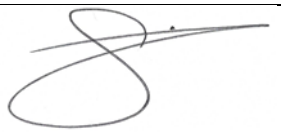
Signature of Authorisor			

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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
V5.0	Amendment of JREO to JRES. Update to procedure section for clarity and to relevant links. Updated Associated JRES documents table.	Georgia Bullock

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Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions		JRESLOG0007 Adverse Events Log

Contents

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1. Background

It is essential that all Adverse Events (AEs) which occur during the course of a study participant's involvement in a research project are appropriately recorded and reported in order to ensure their ongoing safety and well-being.

The UK Policy Framework for Health and Social Care Research (2017) outlines the importance of safety monitoring and of reporting AEs as required.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JRES 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 either institution acting as Sponsor.

3. Scope

This SOP describes the process for recording and reporting Adverse Events or Adverse Incidents for St George's sponsored non-CTIMP studies or for non-CTIMP studies hosted by St George's.

This SOP should be followed for all research which does not fall under the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments. This includes studies involving medical devices, diagnostic products and therapeutic interventions which do not fall within the definition of an Investigational Medicinal Product (IMP).

This SOP does not cover safety reporting for CTIMPs (this is covered in JRESGOVSOP0006).

4. Definitions

For general research management related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023). This includes definitions of an Adverse Event, a Serious Adverse Event and Adverse Incidents.

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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 JRES, of all adverse events that occur at their site.

6. Procedure

All study protocols should include:

- The known side effects of the treatment/intervention.
- Adverse reactions contained within the manufacturer's product information or technical specifications.
- Expected events in relation to the disease or population being studied that will not require expedited reporting.
- When safety reporting for individual participants should commence and end, in relation to consent and the study interventions.
- A detailed explanation of Serious Adverse Event (SAE) reporting procedures and requirements.

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.

The CI can decide how to record and report AEs whether expected or not. They must be recorded in the first instance in the participant's medical notes. The Case Report Forms (CRFs) should also include an AE report where the event should be clearly described. It should be clearly stated in the study protocol and any local SOPs 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. on JRESLOG0007 Adverse

Event Log. The log should be maintained and retained in the Investigator Site File (ISF). The Sponsor may require regular collection or periodic updates of AE occurrence.

Investigators must also consider whether the event qualifies for reporting through the Trust's Adverse Incidents reporting system.

For SGHFT hosted studies, 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

SAEs:

SAEs which are reportable for non-CTIMPS must be:

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

In research other than CTIMPs, a SAE is defined as an untoward occurrence that:

(a) results in death;
(b) is life-threatening;
(c) requires hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity;
(e) consists of a congenital anomaly or birth defect; or
(f) is otherwise considered medically significant by the investigator.

All related and unexpected SAEs must be reported by the CI or Sponsor to the REC 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.

Non-CTIMPs Hosted by St George's:

The PI must follow the instructions provided by the Sponsor of the study for the reporting of SAEs, to ensure safety reporting timelines are met. The PI must retain all correspondence and completed paperwork in the ISF. All SAEs and/or incidents must be documented in the participant's medical records.

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Non-CTIMPs Sponsored by St George's:

The CI should complete the 'Non-CTIMP safety report to REC form' which is available on the HRA website,
https://www.hra.nhs.uk/documents/1087/safety-report-form-non-ctimp.docx

The CI must send the completed form to the REC and must also ensure that the JRES is informed via email (adverseevents@sgul.ac.uk).
This must be completed within 15 days of the CI/Sponsor becoming aware of the event

For investigational studies involving a medical device, the report must **also** be provided to the device manufacturer in accordance with the protocol.

The form and all correspondence will need to be retained in the appropriate section of the Investigator Site File.

The JRES governance team, when notified of an SAE, will check that the report has been received by all relevant parties and will file the completed form and all correspondence in the study e-folder.

7. References

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

UK Policy Framework for Health and Social Care Research (November 2017)

8. Appendices

None associated with this SOP.

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