Standard Operating Procedure (SOP)

SOP Title	Recording and reporting adverse events
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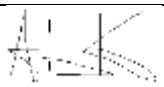
	Name	Title	Signature	Date
Author	Amanda Lilley Kelly	CTRU trial manager		17/05/2019
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Version log			
Version	**Date Approved**	**Reason for Change**	**Author**
1.0			

1.0 Purpose

This guidance document is applicable to all members of the STAMINA team involved in participant care, including clinical oversight.

2.0 Scope

This guidance document will cover reporting of events highlighted during participant contact (STAMINA Programme) with Nuffield Health and NHS professionals. It will outline the STAMINA coordinating centre review process and escalation to appropriate authorities as required. The guidance will also outline clinical oversight via referring healthcare professionals.

3.0 Background

The STAMINA Protocol (WP3) outlines that events will be recorded according to classification;

- Adverse Event (AE): an AE is any study related untoward occurrence that impacts on a participant's health. An example of this might be a minor injury that happens whilst participating in exercise e.g. a muscle sprain.
- Serious Adverse Event: An 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) is otherwise considered medically significant by the investigator.

Events will be monitored between the points of NHS assessments (i.e. baseline assessment to 12 weeks of follow-up). The STAMINA coordinating centre will review all events upon notification and escalate as required in accordance with reporting procedures and timelines.

4.0 Responsibilities

- Nuffield Health Exercise Professionals are responsible for reporting events to the STAMINA coordinating centre within 24 hours (same day) of becoming aware of the event.
- STAMINA coordinating centre are responsible for reviewing events within 24 hours of notification and escalating in accordance with statutory timelines.
- NHS healthcare professionals are responsible for confirming receipt of any safety notifications within 24 hours and outlining any action taken upon notification. In addition any events should be considered during participant 12 week Progress Review (if applicable).
- Principal Investigator should maintain clinical oversight of all events during site participation in project.

5.0 Procedure

5.1 Recording and reporting of events to STAMINA coordinating centre

All events should be reported to the STAMINA coordinating centre within 24 hours (same day) of becoming aware of the event (i.e. participant contact with NH EP).

Events should be reported on the STAMINA Adverse Event CRF, with as much detail as available at the time of reporting. If any additional information becomes available at a later date an updated form should be forwarded to the coordinating centre.

Ensure that details of personnel reporting the event are detailed on the CRF, as if the coordinating centre has any queries related to the event, and associated classification for escalation the coordinating centre will contact relevant personnel involved.

Completed eCRFs should be sent to the STAMINA coordinating centre via NHS.net accounts to sth.stamina@NHS.net. The coordinating centre will confirm receipt within 24 hours (or next working day).

Copies of CRFS should be stored securely in accordance with study requirements (i.e. paper copies stored in a locked cupboard, in a secure room. Electronic copies stored on secured network with suitable encryption.) Any paper CRFs should be returned to the STAMINA coordinating centre at the end of participation.

5.2 Receipt and verification of event reporting

All events will be reviewed within 24 hours (or next working day) of notification, classified and escalated accordingly.

The STAMINA centre will determine causality and expectedness (Related Unexpected Serious Adverse Event - RUSAE) with confirmation from the Chief Investigator. The study team will monitor event reporting for any untoward trends and escalate to oversight groups as required.

5.3 Escalation of event reporting

Events will be escalated in accordance with current governance procedures, within mandated timescales.

5.3.1 NHS Healthcare Professional

NHS professionals (including Principal Investigator) in accordance with the study delegation log will be notified of any events considered clinically significant by the STAMINA coordinating centre in accordance study procedures.

NHS professionals will be asked to confirm receipt of notification and following clinical review confirm any action undertaken to the coordinating centre to complete elements of the Adverse Event CRF.

5.3.2 Oversight Groups ***(Programme Steering Group (PSC) / REC / Sponsor / Funder)***

RUSAEs, deaths and all other safety issues will be included in the safety sections of the reports submitted to the PSC, Sponsor and Funder. (Note that the Sponsor and Funder receive reports via receipt of copies of PSC notes.)

Programme Steering Committee;

It is the responsibility of the PSC to;

- Review all safety data / issues to look for any areas of concern and any emerging trends, including increases in severity or frequency of Adverse Events.
- Report to the Sponsor/Funder in the event of any safety concerns and recommendations relating to continuation of the trial.

Sponsor;

The Sponsor will make the final decision regarding stopping the trial for safety-related reasons, based upon recommendations from the PSC.

Research Ethics Committee;

An annual progress report will be submitted to the approving ethics committee in accordance with mandated timelines. This will include a summary of frequency of events by classification.

6.0 References, Related SOPs, Web links

REC Progress Reports: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/