Appendix 5 Standard operating procedure for reporting serious adverse event and suspected unexpected serious adverse reactions

Introduction and definitions

This document was developed to address the need for a clearly documented pathway for identifying, responding to and reporting serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) during the Positive Choices pilot randomised controlled trial. The document is not exhaustive but aims to cover the main pathways for identifying and handling SAEs and SUSARs.

An SAE includes a situation where any of the following newly affect a trial participant during the trial period:

- death
- hospitalisation
- disability
- congenital abnormality
- life threatening risk

A SUSAR is defined as an unexpected SAE.

Named staff

Role	Named contact
Study manager	Ruth Ponsford (Ruth.ponsford@lshtm.ac.uk)
Principal investigator (PI)	Chris Bonell (chris.bonell@lshtm.ac.uk)
Study steering committee chair	Angela Harden (a.harden@uel.ac.uk)
LSHTM ethics committee chair	John Porter (john.porter@lshtm.ac.uk)

Responsibility and process

Points at which SAE/SUSAR may be detected

1. Cognitive interviews or student surveys
    - During interviews with students
    - During student surveys (pilot, baseline and 16 months follow-up), orally reported to fieldworker
2. Optimisation sessions
    - During focus groups with staff and students
3. Process evaluation
    - During interviews or focus groups with students, staff, parents or trainers
4. Contact with Schools
    - Each year the school will be asked to inform the team of any students within the trial cohort experiencing any of the above SAEs/SUSARs.

Notification process

Potential SAEs/SUSARs will be reported directly to the study manager within one working day.

Once a potential SAE/SUSAR has been reported to the study manager, the following steps will be followed:

- Within 1 working day, the study manager will log the event and notify the PI.
- Within 1 working day, the PI will review the log of the event and advise the study manager whether this appears to constitute an SAE/SUSAR and if so advise the study manager to initiate an SAE/SUSAR form.

- Within 1 working day the study manager will liaise with the school staff member who is the liaison point for that secondary school to investigate the SAE/SUSAR to determine if a safeguarding or other response is required from the school or the research team.
- Within 5 working days, the study manager will liaise with the school staff member who is the liaison point for that secondary school to determine the outcome of the school's investigation of the SAE/SUSAR, and any existing or new actions taken by the school in response to it.
- Within 1 working day, the study manager will finalise the SAE/SUSAR form indicating the outcome of the investigation which will include any further follow-up action required by either the school or the research team.
- Within 1 working day, the PI will review and approve the form and determine whether the event constitutes a SAE/SUSAR which might plausibly have been caused by the intervention or research, which must be submitted immediately to the chairs of the study steering committee and the LSHTM ethics committee, or whether the event constitutes an SAE/SUSAR that is determined not to be plausibly a reaction to the intervention or trial.
- Within 1 working day the study manager files the report in line with the recommendation and copies the report to the PI.

The PI, the study manager and the school liaison staff members will each designate a representative to engage in the above process when they expect to be away from work for 2 or more consecutive working days.

Updating of the SOP

It is the responsibility of the study manger to keep this SOP under review and update it when necessary with advice from the PI.

SERIOUS ADVERSE EVENTS (SAE) AND SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS (SUSAR)

1. DETAILS OF PRINCIPAL INVESTIGATOR

Name	
Address	
Email	
Telephone	
Fax	

2. DETAILS OF STUDY

Full Title of study	
Name of main REC	
Main REC reference number	
Research sponsor	
Reference number for this report	

3. TYPE OF EVENT

Please categorise this event, ticking all appropriate options

☐ Death	☐ Hospitalisation	☐ Disability	☐ Congenital abnormality
☐ Life threatening risk			

4. CIRCUMSTANCES OF EVENT

Date of SAE/SUSAR	
Location (Identification of the SAE/SUSAR)	
Describe the circumstances of the event *(Attach copy of detailed report if necessary)*	
What is your assessment of the plausibility of this event being a reaction to the intervention or trial?	
What safeguarding or other actions have already occurred in response to the event by the school?	
What actions have already occurred in response to the event by other agencies?	
What further actions are indicated and who should be responsible for these?	

5. DECLARATION

Signature of principal investigator	
Print name	
Submission to study steering and ethics committees immediately or annually?	
Date to be submitted	

6. ACKNOWLEDGEMENT OF RECEIPT BY LSHTM ETHICS COMMITTEE

Signature of recipient	
Print name	
Position on committee	
Date	

7. ACKNOWLEDGEMENT OF RECEIPT BY STUDY STEERING COMMITTEE

Signature of recipient	
Print name	
Position on committee	
Date	

Signed original to be filed by study manager
Copies to be submitted to principal investigator and to committees immediately or annually as indicated