Supplementary File 8. Standard operating procedure for reporting serious adverse events/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 Project Respect pilot randomised controlled trial. The document is not exhaustive but aims to cover the main pathways for identifying and handling SAEs and SUSARs.

The standard definition of SAE for trials includes a situation where any of the following newly affects a trial participant during the trial period:

- death
- hospitalisation
- disability
- congenital abnormality of a newborn child of a participant
- life threatening risk

A SUSAR is defined as an SAE that is unexpected. We acknowledge that most of the above risks are unlikely to be reported in a trial of a social intervention. Nonetheless, we will operate to the same standards as are recommended for clinical trials. In the context of this trial of a social intervention, no adverse events are expected. Therefore SAEs and SUSARs are regarded as the same thing.

Named staff

Role	South West named contact	South East named contact
Local study manager	Jo Crichton	Rebecca Meiksin
Local principal investigator (PI)	Rona Campbell	Chris Bonell
Study steering committee chair	David Humphreys	
LSHTM ethics committee chair	John Porter	
NSPCC research ethics committee chair	Nick Drey	

Responsibility and process

Points at which a potential 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. Training
    - During observation of NSPCC-delivered training
    - During analysis of audio-recording of NSPCC-delivered training
    - During observation of all-staff training
    - During analysis of audio-recording of all-staff training
4. Process evaluation
    - During interviews or focus groups with students, staff, parents or trainers
    - During structured observations of curriculum lessons
5. Intervention delivery
    - NSPCC will be asked to notify the research team of any potential events that fall into the standard definition of SAE (defined on p. 1) that they become aware of during intervention delivery.
6. Contact with schools
    - Schools will be asked to notify the research team immediately of any events that fall into the standard definition of SAE (defined on p. 1) that they suspect are related to the intervention. In addition, each year the school will be asked to inform the team of any students within the trial cohort experiencing any of the above events occurring within the trial period.

Notification process

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

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

- Within 2 working days, the local study manager will log the event and notify the local PI.
- Within 1 working day, the local PI will review the log of the event and advise the local study manager whether this appears to constitute an SAE/SUSAR and if so advise the local study manager to initiate an SAE/SUSAR form.
- Within 2 working days the local 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, and whether the SAE/SUSAR might plausibly be a reaction of any form to the intervention or trial.
- Within 5 working days, the local 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 2 working days, the local 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. This investigation will have assessed whether the event was plausibly a response to the intervention or trial.
- Within 3 working days, the local PI will review the form and determine whether the event was plausibly related to the intervention or trial, consulting with the other local PI and, where their expertise was required to make this judgement, with co-Investigators. If they determine that the SAE/SUSAR might plausibly have been caused by the intervention or trial, the event must be submitted immediately to the chairs of the study steering committee, the LSHTM ethics committee and the NSPCC research ethics committee. If the local PI determines the event is not plausibly related to the

intervention or trial, the event will be included within an annual overall report to the chairs of the study steering committee, the LSHTM ethics committee and the NSPCC research ethics committee.

- Within 2 working days the local study manager files the SAE/SUSAR form in line with the recommendation and copies the report to the other local study manager and PI.

The local PIs, the local study managers 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 mangers to keep this SOP under review and update it when necessary with advice from the PIs.

SERIOUS ADVERSE EVENTS (SAEs) AND SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS (SUSARs)

1. DETAILS OF LOCAL 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 event	
Location (Identification of the event)	
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 local 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 NSPCC RESEARCH ETHICS COMMITTEE

Signature of recipient	
Print name	
Position on committee	

Date	

8. ACKNOWLEDGEMENT OF RECEIPT BY STUDY STEERING COMMITTEE

Signature of recipient	
Print name	
Position on committee	
Date	

Signed original to be filed by local study manager

Copies to be submitted to both local principal investigators and to committees immediately or annually as indicated