



Duty of Care and Risk Management Protocol for the Smooth Sailing Study

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Last updated 19th January 2017*

Overview

- The Smooth Sailing Acceptability and Feasibility study will include participants who are high school students, aged 11– 19 years.
- The following Duty of Care and Risk Management Protocol will be used if a research participant self-identifies or self-reports as being at “risk of significant harm” during the study.
- This protocol aligns with the NSW Department of Education “Protecting and Supporting Children and Young People” Policy and the NSW Department of Family and Community Services Mandatory Reporting policies and guidelines.

Risk of Significant Harm

This document will use the definition of “risk of significant harm” as outlined in the NSW Children and Young Person (Care and Protection) Act 1998 and this definition will be applied across all schools involved in the study. Under the Act, a risk of significant harm involves serious threats to safety, welfare, and wellbeing of a child for any of the following reasons:

- The basic physical or psychological needs of the child or young person are not being met (neglect);
- The parents or caregivers have not arranged necessary medical care (unwilling or unable to do so);
- Risk of physical or sexual abuse or ill-treatment (physical or sexual abuse);
- Parent or caregiver’s behaviour towards the child causes or risks psychological harm (emotional abuse);
- Incidents of domestic violence and as a consequence a child is at risk of serious physical or psychological harm (domestic or family violence).
- Students may also be at risk of harming themselves or others, such as reported suicidal thoughts/ plans/ behaviours, or thoughts/ plans/ behaviours in regards to hurting someone else.

The Current Study

Within the Smooth Sailing study, the battery of questionnaires includes the Patient Health Questionnaire (PHQ-9). This questionnaire is used to screen for the presence of depression symptoms. The PHQ-9 also includes one item assessing suicidal ideation (item 9). This item reads “Over the past two weeks, have you had any thoughts that you would be better off dead or of hurting yourself in some way?”. A participant is able to answer either ‘not at all’ (0); ‘several days’ (1), ‘more than half the days’ (2) or ‘nearly every day’ (3). The battery also includes the General Anxiety Disorder Questionnaire (GAD-7) which is used to screen for the presence of general anxiety symptoms. Both the PHQ-9 and GAD-7 are standardised psychological screening measures and as such, may provide an objective measure of anxiety, depression, and suicide risk if completed truthfully. However, further assessment from a trained mental health professional is required for the extent of an individual’s risk to be fully determined. As such, the most appropriate response to elevated scores is to notify a trained mental health professional so that they can follow up with the participant. This is a commonly accepted protocol for mental health research studies. In the context of this study, the trained mental health professional will be the School Counsellor.

Procedure for responding to risk of significant harm:

- 1. When a participant indicates that they are severely depressed/ anxious on baseline or follow-up questionnaires***

When a participant reports that they are experiencing “moderately severe” or “severe” depression or depression, an automatic electronic alert (i.e. email) will be sent directly to the school counsellor. The school counsellor will then be responsible for responding to the alert, following normal school protocols in doing so, including mandatory reporting requirements which may require notifying other relevant individuals (i.e. the school principal or head teacher). The participating schools agree to this protocol before the study commences. To ensure that the school counsellor has adequate weekly time to respond to such alerts, these questionnaires will only be scheduled for completion on a Monday, Tuesday or Wednesday. Over the page is a sample of the electronic alert that the school counsellor will receive:



Dear School Counsellor,

It's the team from Smooth Sailing. Just letting you know that Participant <Study ID> has been allocated to Step 3. This means that they are currently reporting "moderately severe" anxiety and/or depression.

You may already be aware of this student, but we'd like you to touch base with them as soon as possible. They may need a few sessions with you, or to be referred onto other services. Feel free to remind them to use Smooth Sailing; we're here to help!

Please follow your school's policies when responding to this student. Refer to the additional Duty of Care and Risk Management Protocol for more guidance. If you need information about support services, please visit <https://smoothsailing.blackdoghealth.org.au/help#>

The Trial Manager will be making contact with you within 48 hours. If you need any advice or help in responding to a participant, do not hesitate to call the Smooth Sailing team at the Black Dog Institute. You can contact the team via email smoothsailing@blackdog.org.au or phone 02 9382 8509.

Speak soon, The Smooth Sailing Team

The participant themselves will automatically receive access to the Smooth Sailing program which includes a range of psycho-education, help-seeking resources, and online therapy programs, which are evidence-based. Participants will have access to this program for the duration of the trial. An email notification will also be sent to the research team. The research team will then notify the Clinical Advisory Group at the fortnightly meetings. This ensures that the research team can keep track of high scores during the study for adequate reporting. The email alert sent to the Trial Manager is illustrated over the page. **The trial manager will also contact the school counsellor within 48 hours to confirm that the email notification was received and is being acted upon.**



Dear Trial Manager,

Participant <Study ID> has been allocated to Step 3. This means that they have reported moderately severe anxiety/depression. The School Counsellor has been notified. Please document this event and report to the Clinical Advisory Group. Please make contact with the School Counsellor within 48 hours to follow-up on this participant.

The Smooth Sailing Team

2. When a participant reports that they have had “thoughts that they would be better off dead or of harming themselves” at baseline or follow-up

In any instance where a participant reports that they have felt this way for several days or more (i.e. provides a score ≥ 1 to item 9 of the PHQ9), a pop-up alert is shown to the participant. This pop-up will include information for a crisis line, information on a face-to-face service, and advice to tell a trusted adult. In addition, the participant will automatically receive access to the Smooth Sailing program which includes a range of psycho-education, help-seeking resources, and online therapy programs, which are evidence-based. Participants will have access to this program for the duration of the trial.

An automatic electronic alert (i.e. email) will also be sent directly to the school counsellor. The school counsellor will then be responsible for responding to the alert, following normal school protocols in doing so, including mandatory reporting requirements which may require notifying other relevant individuals (i.e. the school principal or head teacher). The participating schools agree to this protocol before the study commences. To ensure that the school counsellor has adequate weekly time to respond to such alerts, these questionnaires will only be scheduled for completion on a Monday, Tuesday or Wednesday. Over the page is a sample of the email alert that the school counsellor will receive.



Dear School Counsellor,

It's the team from Smooth Sailing. Just letting you know that Participant <Study ID> has indicated that they “have had thoughts they would be better off dead, or hurting themselves in some way”, for several days now. This suggests that this individual may be at risk of significant harm.

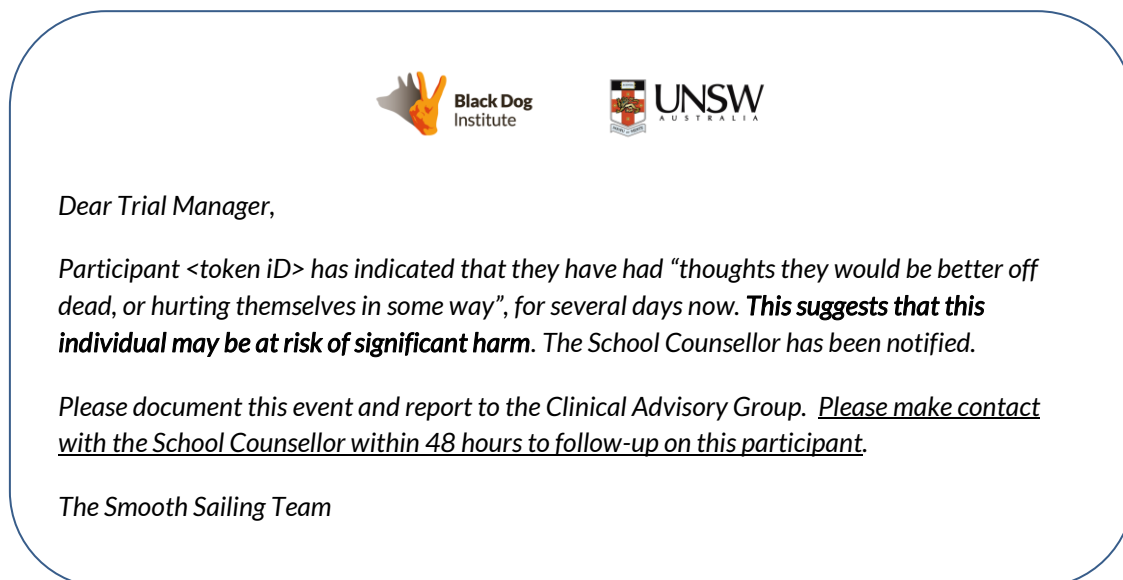
You may already be aware of this student, but we'd like you to touch base with them as soon as possible. They may need a few sessions with you, or to be referred onto other services. Feel free to remind them to use Smooth Sailing; we're here to help!

Please follow your school's policies when responding to this student. Refer to the additional Duty of Care and Risk Management Protocol for more guidance. If you need information about support services, please visit <https://smoothsailing.blackdoghealth.org.au/help#>

The Trial Manager will be making contact with you within 48 hours. If you need any advice or help in responding to a participant, do not hesitate to call the Smooth Sailing team at the Black Dog Institute. You can contact the team via email smoothsailing@blackdog.org.au or phone 02 9382 8509.

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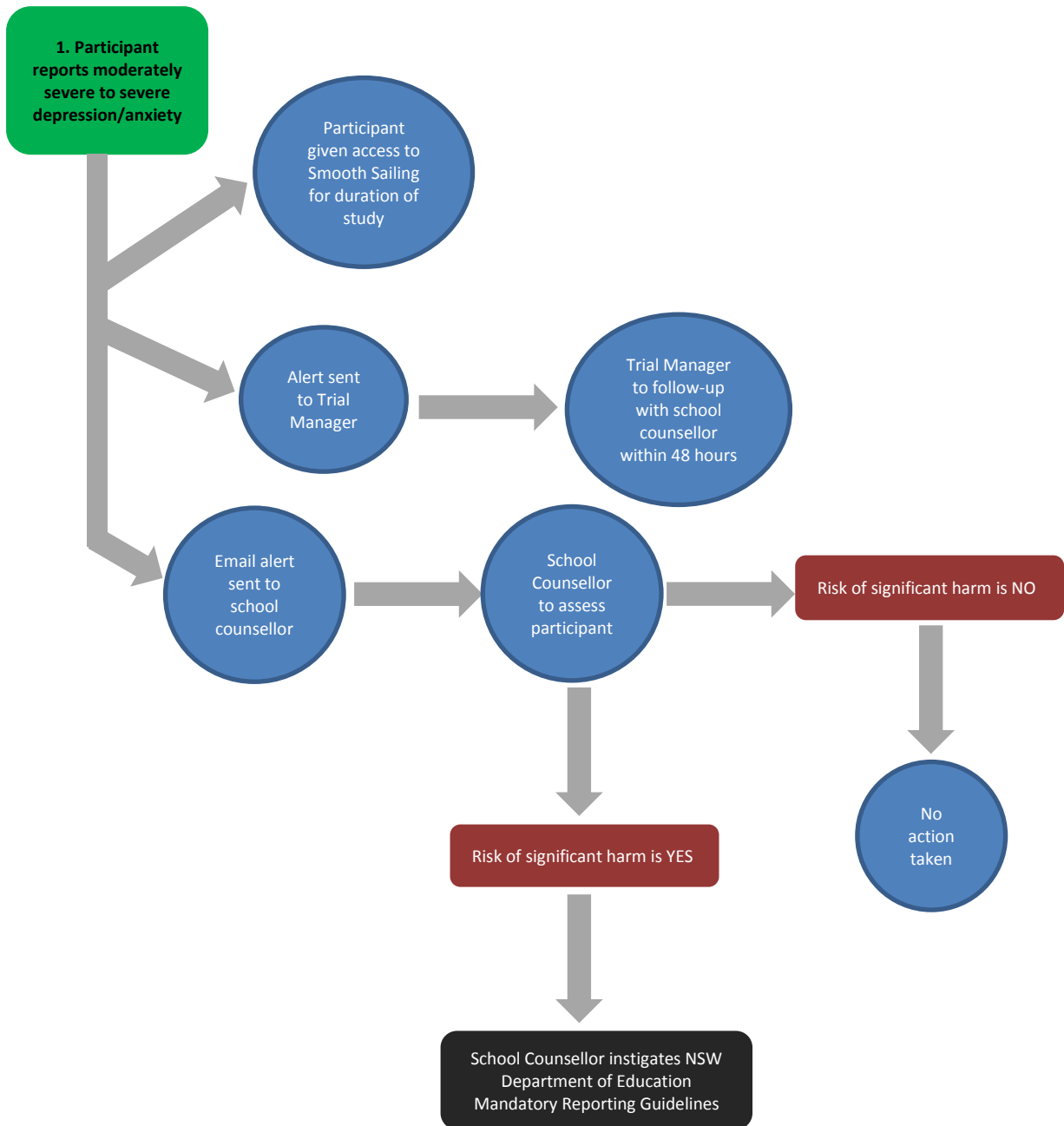
An email notification will also be sent to the research team. The research team will then notify the Clinical Advisory Group of any alerts at the fortnightly meetings. This ensures that the research team can keep track of any adverse events during the study for adequate reporting. This email alert is illustrated below. **The trial manager will also contact the school counsellor within 48 hours to confirm that the email notification was received and is being acted upon.**



3. When a school staff member suspects a participant in the study is at risk of significant harm

If a school staff member suspects a participant in the trial is at risk of significant harm, in any way described above, then normal school protocols will prevail. The school will maintain responsibility and duty of care. To ensure that the research team can keep track of any adverse events, the school will be asked to notify the research team of any participants who school staff has deemed to be at risk. This information will be recorded in an encrypted file stored on the Black Dog Institute UNSW server. The research team will then notify the Clinical Advisory Group for reporting requirements. The Trial Manager will then report to School Counsellor whether the participant needs to be withdrawn.

FLOW CHART OUTLINING RISK MANAGEMENT PROCEDURE



Appendix D – Duty of Care and Risk Management Protocol (Revised 19th January 2017)

