

## CanTalk - Serious Adverse Events Protocol

### Serious Adverse Event (SAE):

A Serious Adverse Event (SAE) is an untoward occurrence experienced by a participant which:

- results in death;
- is life-threatening;
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- is otherwise considered medically significant by the investigator.

### Serious Adverse Events

Suicide intent, self-harm and overdose are highly unlikely, but are associated with major depression and therefore would be an expected SAE. We do not expect treatment to cause the above events. Therefore if any of the following SAEs are reported or observed then the SAE procedure should be implemented as soon as participant safety has been assured.

#### 1. Suicide ideation or intention

Suicide Ideation is characterised by thoughts of suicide without clear intention or plan to attempt suicide. Suicide intention is characterised by intentions or plans to attempt suicide. If participant reports possible suicide ideation or intention they will be assessed for suicide risk using the MINI Section C: Suicidality at screening or the BDI-II during follow ups.

##### a) Low to Moderate risk:

- At home:** They will be encouraged to contact the GP if mood continues to deteriorate. They will be asked for consent to call GP on their behalf and a family member. If they refuse contact with GP or family, but are still at high risk to themselves or others, proceed to call GP
- At Healthcare setting:** Ask the patient to speak with their GP/Oncologist, or see the psychological support services available.

##### b) High risk: (i.e. the participant reports immediate suicide intent):

- At Home:** They will be asked to contact their GP immediately – either themselves or on their behalf. Check if a relative can be contacted. Remain with them until a family member or the GP arrives. Follow up with the research site to inform them of event. Where the participant refuses help and risk is deemed immediately life threatening then the police should be notified.
- At Healthcare setting:** They will be encouraged to contact their GP immediately. Remain with them until a family member or the GP arrives. If in the patient's home, inform research site of event. Where the participant refuses help and risk is deemed immediately life threatening then the police may also be notified.

#### 2. Self-harm

- If participants exhibit any signs of self-harm they will be encouraged to contact their GP that day. In the event that they refuse to seek help and their safety is a concern, their GP will be notified.
- Where the participant refuses help and risk is deemed immediately life threatening then the police should also be notified.

#### 3. Overdose

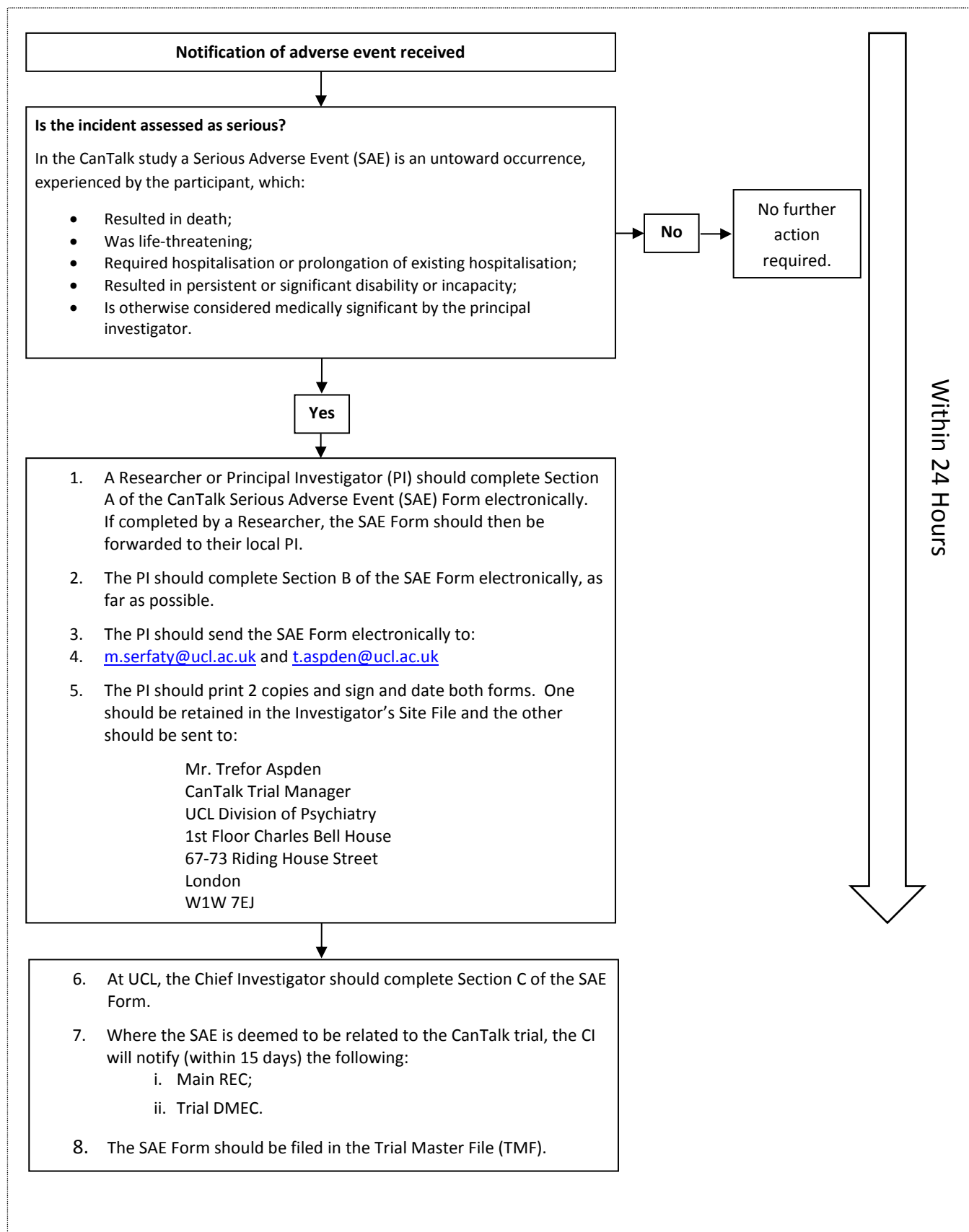
- If the participant reports or exhibits signs of excessive drug consumption/ intention to overdose they will be encouraged to contact their GP that day.
- In the event that they refuse to seek help and their safety is a concern, their GP will be notified.

### Reporting Serious Adverse Events (SAEs)

In accordance with the National Patient Safety Agency's requirements for reporting SAEs, any SAE deemed to be **related** or **unexpected** will initially be reported to the CI, and then David Wilson (sponsor) within 24 hours. After consultation with the CI, a report will be made to the Research Ethics Committee and the study Data Monitoring and Ethics committee within 15 days.

Life threatening or hospitalising medical diagnoses/assessments related to cancer or other physical co-morbidities are considered expected and unrelated SAEs and do not need reporting within 24 hours.

## CanTalk - Reporting serious adverse events (SAEs) Flow Chart



**CanTalk**  
**SERIOUS ADVERSE EVENT (SAE) REPORTING FORM**

<sup>01</sup> Patient's Initials.	<sup>02</sup> Date of Birth.	<sup>03</sup> Participant's Trial No.
<sup>04</sup> Hospital Name.	<sup>05</sup> Responsible Clinician.	

**SECTION A:**

<sup>06</sup>Please indicate below the category which best describes the SAE. <sup>07</sup>Date of SAE:

- 1 = Death
- 2 = Life-threatening (including attempted suicide, overdose, self-harm)
- 3 = Requires hospitalisation or prolongation of existing hospitalisation
- 4 = Results in persistent or significant disability or incapacity
- 5 = Other (considered medically relevant), specify .....

<sup>08</sup>Where did the SAE happen

<sup>09</sup>How did the centre become aware of the incident?

<sup>10</sup>Describe serious adverse event :

**SECTION B: To be completed by the Principal Investigator**

<sup>11</sup>Did this SAE arise as a result of the participant's involvement in the CanTalk trial? Yes  No

<sup>12</sup>Any other comments

<sup>13</sup>Name of PI (print)

<sup>14</sup>Signature of PI

<sup>15</sup>Date

Please print two copies. Please send by post to the address below and retain a copy for the Site File.

Mr. Trefor Aspden  
CanTalk Trial Manager  
UCL Division of Psychiatry  
1st Floor Charles Bell House  
67-73 Riding House Street  
London, W1W 7EJ

**SECTION C: To be completed by Chief Investigator**

<sup>16</sup>Action Take .....

<sup>17</sup>Name of CI (print) .....

<sup>18</sup>Signature of CI .....

<sup>19</sup>Date \_\_ / \_\_ / \_\_\_\_