DUTY: Serious Adverse Event Reporting
Standard Operating Procedure: Cardiff study centre

1. Overview and purpose

This information sheet explains the procedure for reporting Serious Adverse Events (SAEs) occurring in DUTY study participants. Please read the following information carefully: in the event that a participant in the study experiences an event defined as an SAE, you are required to complete a SAE Reporting Form and fax this to the **Cardiff** DUTY Study Manager **Emma Thomas-Jones** on **02920 687 612** within 24 hours of becoming aware of such an event.

2. Definition of Serious Adverse Events (SAEs)

A Serious Adverse Event (SAE) is defined as any untoward and unexpected medical occurrence or effect that fulfils one or more of the following criteria:

- Results in death
- Is life-threatening (refers to an event during which the participant was at risk of death at the time of the event: it does not refer to an event which might have caused death had it been more severe in nature)
- Requires hospitalisation, or prolongation of existing hospitalisation
- Results in persistent and/or significant disability or incapacity
- Represents potentially serious harm to research patients and others.

Please note: you are required to report an event that fulfils any of the above criteria, regardless of whether the event is related or unrelated to activities undertaken as a direct result of participation in the study. If you are in doubt as to whether an event constitutes an SAE and should be reported, please contact the DUTY Study Manager (contact details overleaf).

This procedure should be followed by the recruiter for all SAEs that may occur to a DUTY patient within three months from the date of recruitment (3 months = patient follow-up period).

3. Related and Expected AEs and SAEs

As DUTY is a non-interventional study it is anticipated that most SAEs will be unrelated to study participation, and expected due to the eligibility criteria i.e. acutely unwell child presenting to primary care. If you are responsible for the participant's medical care (GP, A&E clinician, Nurse) and believe the SAE is unexpected, and/or directly related to study participation, please indicate this on the SAE Reporting Form.

4. Procedure for reporting AEs to the Study team

Where the SAE meets one of the categories as defined above, an SAE form should be completed by the responsible clinician, research nurse/researcher and faxed to the DUTY Study Manager within 24 hours of becoming aware of the event.

5. Evaluation & further reporting of AEs

The Chief Investigator(s) and/or clinical member of the study team will assess the nature of the reported SAE, for seriousness and causality and report to the Study Steering Committee. Where the event is defined as an SAE thought to be directly related to the study, the event will be reported to the main Research Ethics Committee (REC) who granted a favourable ethical opinion to the study. All unrelated, expected SAEs will be reported in summarised anonymised form to the funder, sponsor and host institution at agreed reporting intervals.

Following the initial report, follow up data (e.g. discharge diagnosis) may be requested by the DUTY Study Manager. A standard template will be used to record SAEs: instructions as to how to complete this form are given in the following section.

6. Instructions for completing the DUTY SAE Reporting Form

Participant details
Please enter the participant's study ID number.
Please record other participant details as required (date of birth).

Study site details
Please record the recruitment site ID number and/or name.

Event circumstances
Please enter the date on which the event first occurred. Please also use the box provided to give additional details about the event and the circumstances in which it occurred. This detail should include the following (if applicable/known):

- Classification/diagnosis of event
- Cause or likely cause
- Duration of the event
- Any additional descriptive detail available

Please indicate the status of the event (i.e. resolved (and give date), unresolved or ongoing).

Event type
Please select ***one or more*** of the following categories, which best describe the event:

- Event resulting in death
- Life threatening event
- Event requiring hospitalisation or prolongation of existing hospitalisation
- Event resulting in persistent or significant disability/incapacity
- Other important medical condition representing potentially serious harm to research patients and others.

Please indicate whether in your opinion, the event is related or unrelated to participation in the study, and please also indicate, in your opinion, whether the event was expected (e.g. due to the nature of the illness of the presenting child) or unexpected.

Completion details
Please enter your name, role/relationship to the participant (e.g. GP, research nurse) and the date on which the form was completed.

Please fax all completed forms to the secure fax number indicated on the DUTY SAE form within 24 hours of becoming aware of the event:

Emma Thomas-Jones
Study Manager (DUTY) Cardiff
Fax: 02920 687 612
Tel: 02920 687 520 or 511

DO NOT SEND THE DUTY SAE FORM TO ANY OTHER DESTINATION