Paediatric Oncology
UHS

Standard Operating Procedure

Identification of Serious Adverse Events occurring in Paediatric Oncology Shared Care Units linked to the University Hospital Southampton NHS Foundation Trust Paediatric Oncology Principal Treatment Centre

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1. PURPOSE

1.1 The purpose of this SOP is to provide instructions for the identification of any event occurring within, or presenting to, a Paediatric Oncology / Haematology Shared Care Centre (POSCU), that may constitute a Serious Adverse Event (SAE).

2. SCOPE

2.1 The Southampton Paediatric Oncology /Haematology Primary Treatment Centre (PTC) operates a "Shared Care" model for the management of children and young people with malignancies, as outlined as outlined in the "Southampton University NHS Foundation Trust Shared Care Agreement".

2.2 This SOP applies to all POSCUs linked to the Southampton Paediatric Oncology / Haematology PTC.

2.3 The specific purpose of this SOP is to provide a robust mechanism for identifying SAEs in patients recruited to a Clinical Trial of Investigational Medicinal Product (CTIMP), in order that reporting of such events occurs within an appropriate time frame, in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 (UK).

2.4 Although the purpose of this SOP is to identify SAEs in patients recruited to CTIMPs, in order to simplify the process of communication, it will be applied to **all** paediatric oncology /haematology patients seen within the Southampton linked POSCUs (including those not recruited to a CTIMP).

3. DEFINITIONS OF EVENTS

3.1 **Adverse Event (AE):** Any untoward medical occurrence in a subject to whom a medicinal product has been administered including occurrences which are not necessarily caused by or related to that product.

3.2 **Adverse Reaction (AR):** Any untoward and unintended response in a subject to an investigational medicinal product, which is related to any dose administered to that subject.

3.3 **Serious Adverse Event (SAE), Serious Adverse Reaction (SAR) or Serious Unexpected Suspected Adverse Reaction (SUSAR):** Any adverse event, adverse reaction or unexpected adverse reaction, respectively, that:

3.3.1 results in death;

3.3.2 is life-threatening;

3.3.3 requires hospitalisation or prolongation of existing hospitalisation;

3.3.4 results in persistent or significant disability or incapacity, or

3.3.5 consists of a congenital anomaly or birth defect.

4. RESPONSIBILITIES

4.1 The Southampton Principle Investigator (PI) for each CTIMP has responsibility for ensuring that SAEs occurring in patients recruited to the trial are reported to the Clinical Trials Unit (CTU) running the trial. For the majority of paediatric Oncology /Haematology trials this will be the Cancer Research UK CTU, Birmingham.

4.2 The PI is responsible for ensuring that SAEs are reported to the relevant CTU as soon as possible, and no later that 24 hours of becoming aware of the event, unless it is specified within the trial protocol that the particular event does not need urgent SAE reporting. In such instances, this is because the event is expected in the context of the trial treatment, and the PI is then responsible for ensuring that the event is reported to the CTU as an "Expected Serious Adverse Reaction"

4.3 The nominated Clinical Lead within each POSCU is responsible for ensuring that the POSCU team identify any events which may be deemed an SAE and notifies the Southampton PTC as soon as possible, and no later than 24 hours of becoming aware of the event. The POSCU Clinical Lead is not responsible for reporting SAEs to the CTU.

4.4 The nominated Clinical Lead within each POSCU is responsible for ensuring that the extended POSCU clinical team are aware of this SOP and the need to notify the Southampton PTC if a paediatric oncology / haematology is admitted to the POSCU unexpectedly.

5. PROCEDURE

5.1 All new paediatric oncology /haematology patients are issued with a "Paediatric Oncology Parent Held Record" by the PTC at diagnosis. Each Parent Held Record will have a sticker on the front stating:

"Please notify the Piam Brown Clinical Trials Team (02380 795778 – 24 hr answer phone) if this patient is admitted to hospital. This is for trial purposes only and not for clinical advice"

5.2 Each POSCU will be supplied by the PTC with stickers as above which should be used on the front of the patient's POSCU clinical notes, to alert the clinical team.

5.3 The POSCU clinical team should phone the above answer phone if any paediatric oncology /haematology patient is admitted to the POSCU, regardless of whether the patient is on a clinical trial. Any member of the clinical or nursing team may phone the answer phone, they do not need to be on the delegation log for the clinical trial. The following information should be supplied:

5.3.1 the patient's name and date of birth
5.3.2 date of admission to POSCU
5.3.3 Brief description of reason for admission e.g. "febrile neutropenia"
5.3.4 Name of person leaving message

If the POSCU team requires clinical advice about the patient then the PTC clinical team should be contacted directly in the normal manner, in addition to phoning the answer phone above.

5.4 The PTC Clinical Trials team will check the answer phone on a daily basis and will ascertain whether any patients notified are on a clinical trial. The clinical trials team will notify the PTC paediatric oncology / haematology Consultant of the Week, as well as the Southampton PI for any CTIMP that the patient is recruited to, as soon as possible. The

clinical trials team and relevant consultant will decide whether the event requires SAE reporting and will contact the POSCU team for more information if necessary.

5.5 The clinical trials team will keep a record of all phone messages received and this will be periodically audited to check that all SAEs are being captured in a timely manner.