Paediatric Oncology
UHS

Standard Operating Procedure

Data collection and source data verification for Paediatric Oncology /Haematology clinical trials, in which enrolled patients are receiving "Shared Care" in hospitals 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 to ensure the complete and accurate collection of clinical / laboratory data needed for clinical trial patients pertaining to paediatric oncology /haematology patients whose clinical care is shared between the Southampton Paediatric Oncology/Haematology Principal Treatment Centre and a Paediatric Oncology / Haematology Shared Care Centre (POSCU) with the region.

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 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 collecting accurate laboratory and clinical data pertaining to patients recruited to clinical trials whilst their care is being provided within a POSCU. This is to allow the full and accurate completion of the clinical trial Case Report and any Adverse Event forms, and to enable source verification of all data entered.

2.4 Although the purpose of this SOP relates to patients recruited to Clinical Trials of Investigational Medicinal Products (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

4.2 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

4.2 Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

4.2 Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

4.2 Source Data Verification: Process by which the information reported by an investigator is compared with the original records (Source documents) to ensure that it is complete, accurate and valid.

4. RESPONSIBILITIES

4.1. The Southampton Principle Investigator (PI) for each CTIMP has responsibility for ensuring that all CRF and Adverse Event forms are accurately completed and returned to the responsible Clinical Trials Unit. This responsibility is usually delegated to the paediatric oncology clinical trials data managers or research nurse.

4.2 The nominated Clinical Lead within each POSCU is responsible for ensuring that the Southampton Paediatric Oncology / Haematology clinical trials team have access to all data required to allow full and accurate completion of all CRFs and Adverse Event forms.

5. PROCEDURE

5.1 Where possible, the Southampton Paediatric Oncology / Haematology clinical trials team will be granted access to the POSCU electronic pathology system, so that all laboratory data pertaining to patients on CTIMPs can be accessed directly.

5.2 Southampton Clinical Trials team will identify a designated member of the POSCU team (usually the Paediatric Oncology Nurse), who will be the primary contact in terms of access to data pertaining to paediatric oncology / haematology patients.

5.3 The Southampton Clinical Trials team will contact the designated member of the POSCU team for any data that is required for clinical trial purposes, which can not be directly accessed via the POSCU electronic pathology system. This may include copies of all completed chemotherapy prescriptions, laboratory data and details of clinical events.

5.4 All laboratory information that is supplied to the to the Clinical Trials team for completion of CRFs or other trial forms must be provided as either an electronic or printed copy of the laboratory report. Handwritten or poor quality copies of results must not be used as a source of data for completion of the CRF. Faxed copies of documents are acceptable as long as the quality and legibility is good.

5.5 All unplanned admissions to the POSCU must be reported to the Southampton Paediatric Oncology Clinical Trials team (as detailed in separate SOP “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”. In addition, a copy of the POSCU discharge summary for any such admission should be sent (by fax, post or electronically) to the Southampton Paediatric Oncology / Haematology team.

5.6 The Sponsor for a CTIMP or any third party acting on behalf of the Sponsor, or a regulatory authority (e.g. MHRA) may request access to the POSCU for monitoring, inspection or auditing purposes. This may include source data verification as defined above.