University Hospital Southampton NHS
NHS Foundation Trust

Paediatric Oncology
UHS

Standard Operating Procedure

Procedure for The Setting Up Of A New Trial (As A Centre)

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1. PURPOSE

1.1 The purpose of this SOP is to provide instructions for the local set up of a new national trial, and to provide guidance on the procedures and necessary documentation required before a trial may commence at University Hospital Southampton NHS Foundation Trust (UHS) and the subsequent record maintenance.

2. SCOPE

2.1 This SOP applies to all new trials that are to be hosted by the Paediatric Oncology department at UHS, and any staff involved in setting up these trials.

3. RESPONSIBILITIES

3.1 The Principal Investigator (PI) for a trial has the overall responsibility for setting up a trial and ensuring that all necessary local approvals are in place before recruitment starts.

3.2 The responsibility for gaining the necessary local approvals for a national trial to be conducted locally is delegated to the Clinical Trial Co-ordinator (CTC).

3.3 The Trial Sponsor has responsibility for providing the CTC with core documents for obtaining local approval (e.g. Protocol, Information Sheets, REC favourable opinion documents, Clinical Trial Authorisation from the MHRA).

3.4 Staff who undertake any tasks covered by a SOP are responsible for reading, undertaking and adhering to the contents of the SOP.

3.5 All new paediatric cancer trial protocols will have been sent to the Paediatric Oncology Department at Southampton General Hospital for the attention of the Principal Investigator (via CTC) at both concept and final draft stage. It is expected, therefore, that all relevant colleagues will have been involved in discussions about the protocol and will know of its existence. It is recommended that paediatric oncology representatives will have attended an Investigator Meeting prior to, or soon after the opening of any new trial.

4. PROCEDURE

4.1 The PI for the trial must be identified. Once identified they will:

4.1.1 Ensure that there are appropriate medical, paramedical and clerical/data management staff to support the trial within the Paediatric Oncology Department at UHS.

4.1.2 Ensure that there are proper physical location and facilities to undertake the trial efficiently. This will include laboratory facilities and, for biological and pharmacology studies, dry ice, transportation arrangements and other necessary equipment.

4.1.3 Consider formal delegation of duties and these should be documented on the Site Responsibility (Delegation) Log, to be filled in the Investigator Site File (ISF) (it is the CTC responsibility to maintain this document).

4.1.4 Have responsibility for any financial arrangements (as appropriate) for the trial (This will be discussed with the R&D Facilitator at UHS R&D Department).

4.1.5 Will ensure that the UHS R&D Research Governance Officer has signed the formal trial specific contract between the Trial Sponsor of the trial and UHS; and

that signed contract has been forwarded to the Paediatric Oncology Department for inclusion in the ISF (retain a copy for the Site File).

4.2 Submit for ethical approval, Ethics Committee Submission and Approval:

4.2.1 The MREC approval process will be carried out in conjunction with the procedures set out by the R&D department at UHS.

4.2.2 Site Specific Assessment to MREC:

4.2.2.2 Complete the REC form available online (http://www.icr.ac.uk/research/research_divisions/Molecular_Pathology/CLL4_trial/19530.pdf). Confirmation of the Site Specific Assessment will be sent directly from MREC to UHS and the Chief Investigator (CI) of the trial.

4.2.3 In parallel with the submission for Site Specific Assessment, a submission for local R&D approval should also be made using the Request for Sponsorship Form (RfS) from the UHS R&D webpage www.uhs.nhs.uk (see SOP No: PB_TRIAL/SOP/08 for guidance on obtaining UHS R&D approval). *It is worth while checking with the sponsor at this stage about possible start dates for the trial. If it is anticipated that the start date is not in the near future then R&D approval submission should be postponed. This is due to R&D performance being measured on the time from approval to recruitment of the first patient.*

4.2.4 Once both the Site Specific Assessment and R&D approval have been obtained the CTC at UHS will forward a copy of these approvals to the Trial Sponsor.

4.3 The CTC will be responsible for the receipt and distribution of documents issued by the Trial Sponsor. A log must be maintained of all documents received and to whom they are distributed as per UHS procedure.

4.4 The CTC is the Document Controller for the trial and will therefore be responsible for:

4.4.1 Upon receipt of the final protocol completion of the Confirmation of Protocol Documentation Receipt form. Subsequent protocol amendments and instructions to alter existing protocol text will also be issued with this form.

4.4.2 Return original forms, Centre Commitment/ Participation in Trial and Confirmation of Protocol Documentation Receipt to the Trial Sponsor for retention in the ISF.

4.4.3 Retain copies of Commitment/ Participation in Trial form and Confirmation of Protocol Documentation Receipt for the ISF.

4.4.4 Ensure that the ISF is set up according to GCP and Trial Sponsor Guidelines and updated regularly throughout the course of the trial (See SOP No: PB_Trial/SOP/04).

4.5 An initial training session should be held for all staff involved at UHS (clinical and non clinical, pharmacy etc).

4.5.1 The PI or CTC will draw up a list of all personnel who should be invited to the training session(s) and ensure that the list is regularly reviewed and updated to include new personnel. Training sessions should cover key aspects of the protocol and address logistical and resource implications for the trial. A signed record should be maintained of training sessions and attendees. This record must be filed in the ISF.

4.6 Review systems in place to ensure expedited reporting of Serious Adverse Events, as defined in the protocol and in line with the reporting requirements set out in the Standard Operating Procedure on Serious Adverse Event Reporting (SOP No PB_TRIAL/SOP/02).

4.7 Parent/Patient Information Sheets and Consent Forms to be transferred onto UHS headed paper and copies filed in the ISF as per Standard Operating Procedure Preparation and Maintenance of an Investigator Site File (ISF) (SOP No: PB_TRIAL/SOP/04).

4.8 Ensure close liaison with pharmacy in order that all drug supply issues have been resolved prior to commencement of trial.

4.9 The final say on when a trial is open will come from the Trial Sponsor. UHS should be informed in writing and a copy of this should be sent through to the R&D department at UHS.