University Hospital Southampton NHS
NHS Foundation Trust

Paediatric Oncology
UHS

Standard Operating Procedure

Opening a New Trial in an Shared Care Centre (POSCU)

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1. PURPOSE

1.1 The purpose of this SOP is to provide instructions for the set up of a new national trial at a Shared Care Centre (POSCU). This SOP will provide guidance on the procedures and necessary documentation required before a trial may commence at a POSCU and the subsequent record maintenance.

2. SCOPE

2.1 This SOP applies to all new trials in which University Hospital Southampton NHS Foundation Trust (UHS) will act as a Principal Treatment Centre (PTC) for a Paediatric Oncology Trial, and any staff involved in setting up these trials.

3. RESPONSIBILITIES

Please note that a POSCU cannot open a trial until the PTC has opened. A PTC can then open a POSCU at any point deemed acceptable by the Trial Sponsor.

3.1 The Principle Investigator (PI) at the PTC is responsible for the study related activities at the POSCU.

3.2 The Clinical Collaborator (Lead Clinician) at a POSCU is responsible for the clinical procedures relating to the trial, ensuring they follow the treatment guidelines outlined in the trial protocol.

3.3 The Trial Sponsor is responsible for providing the PTC with the correct documentation in order for them to set up a POSCU.

4. PROCEDURE

4.1 The trial needs to be open at the PTC before it can open at a POSCU. However the following activity can take place prior to a POSCU being open:

4.1.1 Any activity that is not trial activity includes:

- Supportive care
- Identification (but not reporting) of Serious Adverse Events (SAEs). If a patient has been admitted to a non-Principle Treatment Centre (non PTC) hospital for an event that may be classified as an SAE, the hospital in question should report the admission to the PTC. The PTC must then notify the Trial Sponsor in accordance with regulations. This should be standard procedure for any hospital admission outside the PTC.
- Follow-up as part of standard care. If patients are being followed-up at a hospital according to the protocol *but also in accordance with standard practice* and the results of these follow-up consultations can be reported to the PTC (via clinician letters) for Case Report Forms (CRF) completion. The trial activity in this process is only the completion of CRFs by the PTC.
- Prescription, dispensing and administration of Non-Investigational Medicinal Products (NIMPs). Information regarding NIMPs delivered in shared care should be collated by the PTC similar to the mechanism for collecting follow up data, and it is the completion of the related CRFs that constitutes the trial activity.
- If an Investigational Medicinal Product (IMP) which would normally be taken by the patient in their own home has been prescribed and dispensed by a

PTC then, should circumstance dictate that the patient attends another hospital, the presence in the hospital is incidental to the fact the patient is on trial (the PTC will need to clarify if an SAE has occurred however). In this scenario the hospital is NOT a POSCU performing research provided the patient is allowed to keep and administer the IMP they arrived with, or the patient surrenders the IMP but it is re-prescribed and the same IMP administered.

- Existing IMP must NOT be stopped in favour of locally prescribed IMP.

4.2 The National Institute for Health Research Coordinated System (NIHR CSP) have agreed a Single Site Specific Information Form (SSIF) approach for a POSCU. Each PTC will receive its own SSIF under its own PI from the Trial Sponsor. Each POSCU that is then associated with that PTC will be covered by the single form, which will need to be signed by the PI at the PTC. The PI at the PTC will then act as PI for each POSCU.

4.3 The Trial Co-ordinator at the Trial Sponsor will upload the signed SSIF for each POSCU cluster to RDMIS CSP Module with the other trial documentation. They will therefore act as the point of contact with regards to setting up the single form for a POSCU.

4.4 The Trial Sponsor will send a Pharmacy File and a Shared Care Centre Site File (mini ISF) to each POSCU. This can sometimes be sent as electronic files on a disk. The POSCU will be required to print of the documents and make up there own hard copy of the ISF.

4.5 Each pharmacy and Clinical Collaborator at a POSCU will receive a full initiation from the Trial Sponsor in the form of a meeting or telephone conference with the Trial Sponsor. The PTC is encouraged to open the POSCUs in batches, so that a single initiation for POSCUs can take place with the Trial Sponsor.

4.6 The PTC must then confirm that the following are in place:

- written agreement between PTC and POSCU,
- copy of R&D approval from POSCU,
- site signature and delegation log from POSCU and is signed off by the PI at the PTC,
- CV and evidence of GCP training form Clinical Collaborator at the POSCU,
- pharmacy initiation at the POSCU has been performed by the Trial Sponsor
- confirmation that Mini ISF and Pharmacy File has been received at the POSCU.

4.7 Once all of the documentation detailed in point 4.6 are in place the PTC are required to notify the POSCU in writing (via email or letter) that they are now ‘active’ and may participate in the trial as per their delegated duties.

4.8 The PTC is then required to fax completed ‘Shared Care Centre Activation Form’ to the Trial Sponsor.

4.9 The Trial Sponsor will then send the PTC an acknowledgement that they have received the ‘Shared Care Centre Activation Form’.

4.10 The PTC must retain a copy of the Shared Care Centre Activation Form and acknowledgement of receipt of this form in the ISF.

4.11 In the event that a POSCU shares care with more than one PTC the Trial Sponsor is not required to perform a full activation more than once; this will occur for the first PTC. Subsequent PTCs will need to provide evidence that all associated regulatory paperwork is in place and to have received confirmation of the same from the Trial Sponsor before their patients may undergo trial related activity in the POSCU.

5. GLOSSARY

The National Institute for Health Research Coordinated System (NIHR CSP)
The NIHR CSP is a system which standardises and streamlines the process of gaining NHS Permission (also known as R&D approval) for commercial or non-commercial clinical research studies in England.

NIHR CSP is also used to process study protocol amendments, or the addition of new sites, for studies that have already gained NHS Permission through NIHR CSP.

Single Site Specific Information Form
As mentioned in point 4.2 the single SSI will be generated by the Trial Sponsor for the PTC. This is essentially a normal Site Specific Information form that will be set up at the PTC but will also cover the POSCU involved in the trial. This has been put in place to simplify the process of local R&D approval allowing the trial to open up at a POSCU allot quicker.

RDMIS CSP Module
The RDMIS CSP Module is the system used by staff across NHS organisations and the Clinical Research Network to support the NIHR Coordinated System for gaining NHS Permission (CSP). It was introduced in stages starting in July 2011.

Trial Sponsor
In most incidences this will be Birmingham Clinical Trials Unit.

GCP Training
Anyone involved in clinical research is required to complete GCP training. This should be updated every three years. The PTC should set up a system to ensure that all clinical staff involved in research within their centre and at a POSCU' have an up to date GCP certificate dated within the last three years.