STANDARD OPERATING PROCEDURE:

Initiation Visit

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SOP SUMMARY

To describe the preparation and procedure to follow prior to, during and following initiation visits.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

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1. BACKGROUND

An initiation visit will be performed for individual studies, prior to the first patient being recruited into that study at a hospital site. Initiation visits may be held for both commercial and non-commercial clinical trials. Prior to initiation visits, all health professionals involved in the study should familiarise themselves with the protocol and highlight protocol procedures that require clarification for discussion during the initiation meeting.

During initiation visits the trial protocol, protocol procedures, important elements of the running of the trial, inclusion/exclusion criteria, case report form completion and sample collection should be discussed and queries clarified.

2. PURPOSE

To describe the preparation and procedure to follow prior to, during and following initiation visits.

3. PROCEDURE

For commercial trials, the initiation visit will be arranged by the pharmaceutical company or Contract Research Organisation (CRO) on behalf of the sponsor. For non-commercial trials, the initiation visit will be arranged by the trial organisers/Sponsor.

The Principal Investigator, research staff working on the study and staff from departments that will be involved in the study should be invited to participate in the initiation visit and be available during the visit where appropriate.

An initiation visit will take place prior to the first patient being recruited into a particular clinical trial at a hospital site.

3.1 Preparing for the Initiation Visit

- All approvals and regulatory documentation should be in place to open the study at site.
- This includes a favourable site specific assessment, and agreement of staff capacity to run the study at site
- The Research Teams should familiarise themselves with the trial protocol and make a record of any element of the protocol which is unclear and would need further clarification during the visit
- All Research Teams working on the study, Principal Investigator and personnel from departments supporting the study should be informed that the initiation visit is scheduled and be invited to attend
- A room should be booked for use during the visit

3.2 During the Initiation Visit

- The trial protocol, protocol procedures, important elements of the running of the trial, inclusion/exclusion criteria, case report form completion and sample collection should be discussed and queries clarified
- The Principal Investigator, research staff working upon the study and staff from departments that will be involved in the study should attend the initiation visit where appropriate
- Any documentation (e.g. Trust approval, delegation log etc.) that is required by the pharmaceutical company/trial organisers/Sponsor that has not already been collected, should be provided

- As appropriate, the pharmaceutical company/trials organisers/Sponsor should provide any documentation that has not already been sent to the site (e.g. site file, case report forms etc.)

3.3 Following the Initiation Visit

- The pharmaceutical company/trials organisers/Sponsor should submit a written report to the Principal Investigator summarising what was discussed during the initiation visit
- The written report should be filed in the Study Site File
- A member of the Research Team should seek to address promptly any outstanding actions that arose from the initiation visit

4. OTHER RELATED PROCEDURES

None