

Standard Operating Procedure

Title: ORGANISATION AND PLANNING

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1. BACKGROUND

It is essential that the procedure for planning and organising studies be documented to ensure consistent practice throughout the Trust.

2. PURPOSE

To provide a detailed overview for the organisation and planning of each study undertaken in Wirral University Teaching Hospital NHS Foundation Trust.

3. OTHER RELATED PROCEDURES

SOP 006 Study Files and Filing
 SOP 010 Adverse Event and Serious Adverse Event Reporting
 SOP 014 Pre-Study Site File Check

4. WHEN

All individuals to be involved with a study should be identified as early as possible to enable time for them to familiarise themselves with the protocol.

Each hospital Trust running a study must ensure that they have the necessary resources to run it safely and to the appropriate standards.

5. WHO

It is always the responsibility of the Principal Investigator to ensure that a study is performed according to ICH Good Clinical Practice guidelines and legal requirements. This responsibility cannot be transferred.

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Each study will be the responsibility of a named Research Practitioner. This individual will be identified in the study file.

6. HOW

6.1. Pre-study

The nominated Research Practitioner will obtain approval to conduct the study from each hospital Trust involved.

The Research Practitioner will set up the study file (as described in SOP 006) to be kept at site.

The Investigator will discuss recruitment targets with the Sponsor.

6.2. During the study

The Research Practitioner will provide progress reports on study activity as required (Sponsor, Research Ethics Committee, Trust Research and Development Office).

6.3. End of study

The Research Practitioner will ensure the study is formally closed and appropriate bodies notified, i.e. Sponsor, Medicines & Healthcare products Regulatory Agency, Research Ethics Committees and Trust Research and Development Office.

The R&D office will assist in archiving of study documentation.

The Research Practitioner will arrange for return of any study material required by the Sponsor.

6.4. General Provisions

Serious adverse events, Suspected Unexpected Serious Adverse Reactions and adverse events should be followed up by the Investigator, even after the study has closed and reported to the necessary regulatory bodies (see SOP 010).

Outpatients involved in a study should be provided with 24 hour contact details in case of emergency.

Medical records should clearly indicate participation in a clinical study by documenting it on the alert label on the inside of notes, or on medical history sheets in a manner that complies with local hospital policy.

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The GP of study participants should be informed in accordance with Local Research Ethics Committee guidelines and patient's consent.