

Standard Operating Procedure

Title: STUDY TEAM – DEFINITION OF RESPONSIBILITIES

| REF: SOP 002 | Version: 04 | Issue No: 1 |
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| Reviewed by: Professor Rod Owen | | Date: 05/11/2009 |
| Approved by: Dr M J Maxwell | | Date: 21/05/07 |
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| This SOP is effective from: | | Replaces: Version 03 (21/05/07) |

1. BACKGROUND

A research study requires appropriately qualified personnel to ensure that it is run smoothly and correctly. Research personnel involved in a research study include, but are not limited to:

- Chief Investigator
- Principal Investigator
- Co-Investigator
- Research practitioners (such as research nurses)
- Study co-ordinators (e.g. data managers)

There may also be staff that are associated with, but not directly involved in the research study, such as:

- Clinicians
- Specialist nurses
- Pharmacists
- Laboratory staff
- Support staff

For a study to run smoothly it is essential for all staff involved to be aware of the anticipated extent of their involvement, and the limits of their authority. ICH Good Clinical Practice Guidelines define an investigator as “*A person responsible for the conduct of the clinical trial at a trial site.*” The investigator is responsible for protecting the integrity, health and welfare of the study subjects during the study. The investigator must be:

- Qualified by education, training and experience and for clinical trials, legally allowed to practice medicine.
- Thoroughly familiar with the study protocol and the investigational product(s).

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- Aware of, and comply with Good Clinical Practice and any applicable regulatory requirements pertaining to clinical trial conduct.

The Chief Investigator is defined as the lead investigator for a single site study, or in relation to a study conducted at more than one site, the investigator who takes primary responsibility for the conduct of the study across all sites. The Principal Investigator is defined as the authorised health professional responsible for the conduct of that study at a study site, and if a team of authorised health professionals at a study site conducts the study, the Principal Investigator is the leader responsible for that team. In these SOPs the term Principal Investigator is used as defined above, however (s)he may also be the Chief Investigator for a particular study. Other investigators at the same site are Co-Investigators or Sub-Investigators. The term Investigator in these SOPs refers to the Principal Investigator and all Co-Investigators.

2. PURPOSE

To assist in the division and allocation of responsibilities and to clarify boundaries of responsibility within the local study team, to ensure smooth running of the study. To provide the Sponsor with an overview of the division of responsibilities within the study.

3. OTHER RELATED PROCEDURES

All SOPs

4. WHEN

The initial allocation of responsibilities is one of the first tasks in the pre-study phase.

5. WHO

During the pre-study phase, the Principal Investigator, co-investigator(s) if applicable and the assigned research practitioner responsible for the study must discuss and agree on the study requirements with the representative from the sponsor if appropriate. The tasks that can be delegated will depend on the qualifications and experience of the individuals, and may vary from study to study.

6. HOW

Each study will have a Site Principal Investigator (unless approved as a 'no local investigator' study) who has overall responsibility for:

- The welfare of patients
- Conduct of the study
- Administration of drugs
- Ensuring the local management needs are met

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Ensuring that the requirements of the Central Office for Research Ethics Committees, the Site's Trust Research & Development Department and the The Principal Investigator should, where required, allocate day-to-day responsibility to one member of the department – known as the study responsible person.

The study responsible person should, with the Principal Investigator where required, discuss and agree the allocation of tasks with the staff members. The allocation of tasks should be recorded as a "Delegation of Authority" log, with specimen signatures and initials of all involved. Form 1SOP002 should be used for this purpose, unless supplied with an appropriate alternative by the Sponsor.

The Sponsor should be made aware of the planned division of tasks. Contact names and roles of other individuals involved in the study (e.g., Pharmacy, laboratory staff) should also be communicated to the Sponsor.

The study responsible person, with the Principal Investigator where required, should appraise the need for additional staff, and discuss changes with the Sponsor.

Where there is a **medically qualified** co-Investigator, he or she may normally:

- Screen and recruit patients
- Obtain informed consent from potential study subjects
- Confirm eligibility of study subjects
- Sign prescriptions
- Sign off Case Report Forms
- Conduct clinical examinations, evaluate laboratory and other reports and carry out any assessments of a medical nature.

Where there is no medically qualified co-investigator, the study responsible person will usually be the Research Practitioner. Unless otherwise specified, a Research Practitioner will not conduct these activities, though assistance with them may be given. Obtaining informed consent from study patients however, will **never** be conducted by the Research Practitioner, unless the study is a non-interventional study that does not involve drugs or other treatments, or there is no randomisation to therapeutic modalities and if the Research Practitioner is competent and duly authorised by the Principal Investigator to do so. The Research Practitioner may participate in the discussion of the study with the prospective subject even when not permitted to obtain consent. The Research Practitioner will usually be responsible for:

- Screening and recruitment of patients
- Discussing study with potential study subjects
- Maintaining study specific paperwork and study file
- Planning and booking subject appointments as required
- Updating recruitment data
- Attending appropriate multidisciplinary team meetings
- Communicating with sponsor on progress of study
- Liaising with network personnel regarding the progress of research studies

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Any tasks identified as outside the scope of normal practice of a research practitioner should be discussed with central and local management as appropriate.

NAME OF TRUST: _____

STUDY TITLE: _____

DELEGATION OF AUTHORITY AND SIGNATURE LOG

SITE PRINCIPAL INVESTIGATOR NAME: _____

| As the site Principal Investigator for the above study, I authorise the following staff to assume the indicated responsibilities, and give assurance that I am satisfied the staff have the competency to undertake these responsibilities: | | | | | | |
|---|------|-----------|-----------------|-------------------------|----------------------|--------------------|
| PRINT NAME | ROLE | SIGNATURE | SIGNED INITIALS | STUDY RESPONSIBILITIES* | FROM (dd/mm/yyyy) | TO (dd/mm/yyyy) |
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*Study Responsibilities:

- A: Screening Patients B: Obtaining Informed Consent C: Study Record Completion D: Blood sample collection
E: (please specify) _____ F: (please specify) _____
G: (please specify) _____ H: (please specify) _____

Start of Study: _____
Site Principal Investigator signature

Date: _____

End of study: _____
Site Principal Investigator signature

Date: _____

