Dorset HealthCare University NHS Foundation Trust

# Standard Operating Procedure for Site Staff Responsibilities

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| **Objectives** | This SOP outlines the responsibilities of research study site staff. |
| **Scope** | This procedure is applicable to all staff involved in a research study. |
| **Responsibility** | It is the responsibility of the Principal Investigator to ensure that this SOP is adhered to. |
| **Related Document** | None. |



## 1 Purpose

This SOP defines the allocation of responsibilities and clarifies boundaries of responsibility within the research study teams and to the sponsor.

## 2 Introduction

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

- Chief Investigator
- Principal Investigator
- Co-Investigator
- Research nurses/practitioners
- Study co-ordinator

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

Staff must be aware of the anticipated extent of their involvement and limits to 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:

- An authorised healthcare professional; however they do not have to be a medically qualified Doctor (as stated in Regulation 2 of SI 2004/1031);
- Thoroughly familiar with the study protocol and the investigational product(s);
- Aware of and compliant with Good Clinical Practice and any applicable regulatory requirements pertaining to clinical trial conduct.

The Chief Investigator (CI) is defined as the lead investigator for a single 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.

The Principal Investigator (PI) is defined as the authorised health professional responsible for the conduct of that study and the study team **at a study site.** The PI may also be the CI for a particular study. Other investigators at the same site are co-investigators or sub-investigators. Here, the term ‘investigator’ refers to the PI and all sub-investigators.

# 3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section.

# 4 Revisions

This is the second version of this SOP. Section 5 updated with the current job roles within the DHC R&D department.

# 5 Procedure

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

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**5.2** During the pre-study phase, the PI, co-investigator(s), research nurse/practitioner(s) and study co-ordinator(s) responsible for the study must discuss and agree on the study requirements with the body responsible for the study, 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.

**5.3** The PI should, where required, allocate day-to-day responsibility to one member of the department (study co-ordinator).

**5.4** The study co-ordinator should, with the PI where required, discuss and agree the allocation of tasks with staff members. The allocation of tasks should be recorded on a 'delegation log' with signatures and initials of all involved.

**5.5** The study organising body should be made aware of the planned division of tasks. Contact names and roles of other individuals involved in the study (e.g. pharmacy and laboratory staff) should also be communicated to the study organising body.

**5.6** The study coordinator, with the PI where required, should appraise the need for additional staff and discuss changes with the study organising body.

**5.7** A suitably qualified person designated by the PI and agreed by the CI may:

- 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
- Manage Investigational Medicinal Products (IMP)

**5.8** The Principal Investigator holds ultimate overall responsibility for the study at the site. In some instances the nurse may be the PI. Both nurses and doctors are subject to professional accountability and professional codes of conduct, ensuring that they practice within their competency.

**5.9** The Research Nurse/Practitioner will, in addition, be responsible for:

- Planning and booking subject appointments as required
- Updating recruitment data
- Attending appropriate multidisciplinary team meetings
- Communicating with study organising body on progress of study
- Liaising with network personnel regarding the progress of research studies

**5.10** The lead Research Nurse/Practitioner for each trial will in addition be responsible for:

- Ensuring that the trial office has supplied sufficient clinical consumables and all of the necessary paperwork.

**5.11** The Study Coordinator/Research Support Coordinator/ Research Practitioner may be delegated responsibility for:

- Submissions for local approvals
- Local management of Investigator Site File and Essential Documents
- Completion of case report forms and data queries

**5.12** The pharmacy team may be delegated certain duties involved with IMP management, but the overall responsibility for the IMP at the site remains the responsibility of the PI. Accountability logs must be maintained by the delegated pharmacy staff.

# 6 Appendices

There are no appendices to this SOP.

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# 7 Responsibilities

During the pre-study phase, the PI, sub-investigator(s), study co-ordinator(s), research nurse/practitioner(s) and responsible for the study must discuss and agree on the study requirements with the body responsible for the study, 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. All staff must adhere to this SOP.

# 8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

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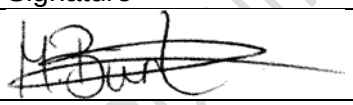
| Hazel Burt |  | 12/04/19 |
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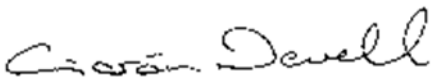
| Dr Ciarán Newell |  | 12/04/19 |
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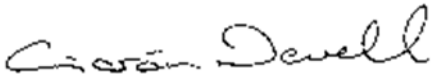
| Dr Ciarán Newell |  | 12/04/19 |