

# STANDARD OPERATING PROCEDURE

## STH Researcher

### Delegation of Study Duties

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<i>Approved by</i>	Research Manager

## Standard Operating Procedure

### Delegation of Study Duties

This SOP has been produced in accordance with ICH/GCP Guidelines and the DoH Research Governance Framework 2005. This SOP will outline the procedure for the delegation of study duties.

#### Background

The Investigator has overall responsibility for the proper conduct of the study; however trial duties may be delegated to appropriately qualified staff.

#### Definition

A study duty is a task essential to the conduct of the study that is documented in the study protocol. A Delegation of Study Duties Log records all delegated duties.

#### Process

##### 1. Knowledge, training and experience

- 1.1 The Investigator must provide appropriate training or provide access to appropriate training for delegated duties.
- 1.2 The Investigator will ensure the appropriateness of the personnel undertaking the duties, by ensuring that up to date CVs of all personnel reflect requisite skills and education. The CVs of staff involved in research (e.g. research nurses, study co-ordinators, medical staff, research associates and study administrators) must be filed in the Investigator Site File.
- 1.3 The Investigator has a responsibility to ensure prior to the delegation of a study duty, that the study personnel concerned have a good knowledge and understanding of the trial protocol (and investigational product, where applicable) and are competent to undertake the delegated task.
- 1.4 Study personnel must keep an up to date training record in relation to study duties.
- 1.5 All personnel involved in the clinical research must practice within their own code of professional conduct. Study duties must not jeopardise professional practice and accountability.

##### 2. Procedure

- 2.1 The Investigator must comply with section 4.1.5 of ICH/GCP which specifies a list, which is kept in the Investigator Site File. The list should identify all the suitably qualified persons to whom the investigator has delegated significant trial related duties. (**Appendix 1** Specimen Delegation of Study Duties Log).
- 2.2 The Sponsor of the study at the time of study set up will agree with the investigator the duties to be delegated. The range of duties to be delegated will vary between sponsors some sponsors will allow more flexibility than others.
- 2.3 The Investigator records the study personnel and the duties delegated to them on the Delegation of Study Duties Log, which is filed in the Investigator Site File.
- 2.4 All personnel accepting a delegated duty sign and initial against each duty identified on the Delegation of Study Duties Log.
- 2.5 The investigator must sign and date to validate all entries to the Delegation of Study Duties Log.
- 2.6 The Investigator will update and amend the Delegation of Study Duties Log if delegated duties or personnel change during the course of a study.

STH Study No:	
Study Title:	
Investigator Name:	

Title/Full Name	Job Title/Study Role <sup>1</sup>	Signature	Initials	Key delegated study tasks <sup>2</sup>	Duration		Principal Investigator Signature
					Start Date	End Date	

<sup>1</sup> Identification of study role includes but is not limited to sub-investigators, study nurses, pharmacist (when appropriate) and data recorders. List individuals delegated significant study-related tasks (ICH GCP 4.1.5). Signatures/Initials required for all persons authorised to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24).

<sup>2</sup> Identify key study tasks when delegated by the investigator. Examples of key delegated study tasks could include: 1=Provision of Patient Information; 2= Informed Consent 3 =Inclusion/Exclusion Assessment; 4=Obtain Medical History; 5=Perform Physical Exams;6= Prescribing; 7=CRF Completion; 8=CRF Signature; 9=Investigational Product Accountability; 10=Drug Dispensing; 11=Archiving; 12=Data Query Completion;

## Appendix 2- Associated Documents

	Document	Research Department network drive	Website	Database	Created by
1	Personnel Log and Delegation of Study Duties Log	<a href="#">.Directory\Research Governance\Project Authorisation\Templates\Site file documents</a>	Yes	N/a	PC