



Delegation Log

Instructions

To comply with ICH GCP section 4.1.5, Investigators should maintain a list of appropriately qualified and trained persons to whom the Investigator has delegated significant trial related duties.

This Delegation Log is to be used by the Principle Investigator to delegate study-related tasks to the Coordinator/s. It can be amended to suit the needs of the study (e.g. delegation to other Study Management Team members) and should be updated when there are any staff changes.

Study name					
Grant ID number		Trial ID number			
Principle Investigator [Name and contact details]					
Primary contact person [Name and contact details]					
	TASKS				
	Recruitment and Enrolment*	Data Collection and Management +	Maintenance of source^ documents	HREC submissions and communications	Other (please specify)
[Name]					
[Name]					

As the Principle Investigator (PI) for the above-mentioned study, I have authorized the following staff to assume the indicated study-related tasks for which they are qualified by means of training and experience. I understand that this in no way alters my responsibilities as defined by ICH GCP, applicable regulations and the clinical trial agreement.

Signature of Principle Investigator:

Date: _____

As the Coordinator for the above-mentioned study, I confirm I have been appropriately trained to perform the indicated study-related tasks.

Name of Coordinator:

Signature of Coordinator:

Date: _____

*** Recruitment and Enrolment may include:**

- Screening subjects for eligibility (including medical history review)
- Performing the informed consent process and obtaining written informed consent
- Patient enrolment

+ Data collection and management may include:

- Case Report Form (CRF) entries
- CRF corrections
- Data query resolution
- Confirmation of completeness and accuracy of data collection
- Archive functions

^ Source documents are the original documents from which information was extracted (e.g. patient records from hospital or General Practice).