STANDARD OPERATING PROCEDURE:

Definition of Responsibilities for Externally Sponsored Studies

SOP REFERENCE NUMBER	CLPG19 SOP 6
VERSION NUMBER	Version 1
REPLACES SEPT DOCUMENT	
REPLACES NEP DOCUMENT	SOP: Definition of Responsibilities for Externally Sponsored Studies v2
KEY CHANGES FROM PREVIOUS VERSION	Updated cover sheet – merger. Updated delegation log format
AUTHOR	Research & Development Manager
CONSULTATION GROUPS	
IMPLEMENTATION DATE	
AMENDMENT DATE(S)	
LAST REVIEW DATE	
NEXT REVIEW DATE	
APPROVAL BY CLINICAL GOVERNANCE & QUALITY SUB-COMMITTEE	March 2018
RATIFICATION BY QUALITY COMMITTEE	April 2018
COPYRIGHT	

SOP SUMMARY

This Standard Operating Procedure describes the process for allocating roles and responsibilities for clinical trials hosted by the Trust, via a delegation log.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

STANDARD OPERATING PROCEDURE:

Definition of Responsibilities for Externally Sponsored Studies

CONTENTS

1. BACKGROUND

To ensure the smooth and accurate conduct of research studies appropriately qualified personnel are required. This may include staff directly involved in the conduct of the research such as:

- Principal Investigator
- Co-investigator
- Research practitioners (e.g. research nurses/practitioners/officers/co-ordinators)
- Study co-ordinators (e.g. data managers/research assistants)

In addition there may be staff associated with, but not directly involved in the research trial including:

- Clinicians
- Specialist nurses
- Pharmacy Staff
- Laboratory staff
- Other Support staff e.g. radiology

For a trial to run safely it is essential that all staff involved are 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 trial subjects during the trial. The investigator must be:

- Qualified by education, training and experience and legally allowed to practice medicine
- 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

If a team of investigators conducts a trial at a trial site the investigator responsible for leading the team is usually referred to as the Principal Investigator (PI). Other investigators are referred to as co-investigators or sub-investigators. The term investigator in this SOP refers to the PI 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 the smooth running of the trial. Will also, where applicable, provide the Sponsor with an overview of the division of responsibilities within the trial.

3. PROCEDURE

During the pre-study phase, the Principal Investigator, co-investigator(s) if applicable and the assigned research practitioner responsible for the clinical trial must discuss and agree on the study requirements with the representative from the Sponsor company if appropriate. The delegation of tasks will depend on the qualifications and experience of the individuals in the team, and may vary from study to study.

Individual trial related duties and functions should be defined, established and allocated prior to the initiation of a trial.

Each trial will have a Principal Investigator, who has overall responsibility for:

- The welfare of patients
- The medical care of trial subjects
- Informed consent
- Conduct of the study in compliance with the protocol
- Administration and management storage of investigational product as appropriate
- Ensuring that local management needs are met
- Obtaining approval of and continued communication with regulatory bodies e.g. Ethics Committee and Trust management
- Safety reporting e.g. Adverse Events and Serious Adverse Events
- The accurate and timely completion of trial data
- Archiving

The PI can nominate an appropriately experienced person, for example Research Nurse or Clinical Trial Practitioner, to assist in the management of the trial at the investigational site. This person along with the PI, where required, will discuss and agree the allocation of tasks with staff members. The allocation of tasks to appropriately qualified persons should be recorded on a Study Delegation Log (SDL)/Site Responsibility Log (SRL) with specimen signatures and initials of all involved. See Appendix A.

The SDL/SRL will:

- List names of staff delegated to each procedure
- Be up to date
- Be signed and dated by the investigator, supplied to the sponsor company if applicable and updated as required throughout the trial
- Be filed appropriately in the investigator site file. If archived by sponsor ensure copy remains at site.
- Should be updated as new staff are recruited, but superseded versions must not be destroyed in order to provide an audit trail for future inspection.

The external Sponsor should be made aware of the planned division of tasks. Contact names and roles of other individuals involved in the trial (e.g. Pharmacy, laboratory staff) should also be notified to the Sponsor. The PI along with the research nurse/clinical trial practitioner/officer/co-ordinator should review the need for additional staff, and discuss changes with the Sponsor as appropriate on an ongoing basis.

Some trial related responsibilities may be delegated to appropriately qualified personnel according to local practice, this will be documented on the SDL and signed and dated by the PI. Refer to the table in Appendix B re tasks commonly associated with Clinical research team roles.

4. OTHER RELATED PROCEDURES

All other Research SOPs

5. APPENDICES

Appendix A: Delegation of Duties Log
Appendix B: Approved Responsibilities of Site Staff

Appendix A

Delegation of Duties Log

Study Number:		Study Title:		Site ID:	

Investigator Name:	

Legend

Use this legend to complete the General Duties column. For each individual listed in the Name column, enter the letter(s) (e.g., a c, e) from the legend below that correspond to their protocol-related duties in the General Duties Column. If there are significant protocol related duties that are not already included in the legend, add them in the empty spaces provided below.

1. Obtain informed consent	**8. Query completion**	
2. Obtain medical history	**9. Maintain Regulatory Docs**	
3. Perform Physical exam	**10. Maintain IRB documents**	
4. Assess Eligibility Criteria	**11. Data Monitoring**	
5. Dispense Study drug / Device	**12. Safety monitoring**	
6. CRF completion	**13. Take blood sample**	
7. CRF Queries	**14. Refer patient to study team**	

The principal investigator should sign below during the Site Close-Out Visit.

I have reviewed the information on this log and have found it to be accurate. All delegated duties were performed with my authorisation.

Principal Investigator Signature: _____Site Close-Out Visit Date: _____

Delegation of Duties Log

Study Number:		Study Title:		Site ID:	

Investigator Name:	

This log should include the Principal Investigator, subinvestigator(s), trial/study coordinator(s), and all other clinical staff who routinely see trial subjects or who have specific data collection/interpretation duties. This log should also include any contracted specialists performing protocol-required examinations. Add new or replacement staff as appropriate.

Name (please print)	Trial Role	General Duties (see legend)	Initials	Signature	Principal Investigator Signature	Date of Duties	
						From (dd-MMM-yyyy)	To (dd-MMM-yyyy)

APPENDIX B

*APPROVED RESPONSIBILITIES OF SITE STAFF

*This is not an exhaustive list and will require annotating at a local level to take into account local Network practices and policies.

Position	APPROVED RESPONBILITIES OF SITE STAFF
Co-investigators	Medical care of patients Screening of patients for eligibility Informed consent Sign consent form Randomisation Responsible for administration of study drug Responsible for collection of trial specific blood samples Completion and return of CRFs and providing responses to data queries Prescriptions Timely SAE reporting Ethics committee obligations Other as locally applicable;
Research Nurse/ Clinical Trial Practitioner	Screening of patients Informed consent (according to local practice) Randomisation Completion and return of CRFs Data queries Documentation of adverse events in source data Investigator/Study file set up and management Support monitoring visits and audits and inspections Preparation of paperwork for Ethics committee/R&D Preparation of SAE reports for medical input and causality assessment Taking and shipping of trial related samples Other as locally applicable; Notification to Scanner Centre and Medical Physics of studies involving investigations that require a radiation dose (e.g. bone scans, MUGA scans, CT scans). Provide request forms for these investigations which carry a sticker to show whether the investigation falls within standard practice or is purely a requirement of the clinical trial.
Data Manager	Data entry Completion and return of CRFs Data queries Support monitoring visits, audits and inspections Other as locally applicable;

(Research) Pharmacist	Acknowledge receipt of trial supplies Drug accountability and monitoring of compliance Dispensing of Investigational Product to patients Complete dispensing logs Maintain Pharmacy file Monitor storage of Investigational Product Other as locally applicable;

PI Signature: _____ Date: _____