Title: UCLH SOP 2: Definition of Responsibilities

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Revision Chronology:			
Version Number:	**Effective date:**	**Reason for change:**	**Author:**
1	26/09/2014	First version includes UCLH standardisation.	Shivali Trivedi
2	18/12/2017	Entire SOP updated to reflect current processes; additional detail and clarification provided; updated to current UCLH SOP template. Reviewed by: Isla-Kate Morris, JRO Quality & Safety Manager; Mona Hassan, JRO Research Audit & Oversight Officer; and NIHR CRF QA Manager, Selvy Raju.	Shivali Trivedi
3	21/12/2023	Updated the good documentation practices to align with current procedures. Added CI responsibilities during pre-study phase. Amended the links listed under references.	Ummulkheir Ayub

ACRONYMS

CCTU	Cancer Clinical Trials Unit
Co-I	Co-Investigator
CRF_1	Case Report Form
CRF_2	Clinical Research Facility
CTA	Clinical Trials Assistant
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTP	Clinical Trials Practitioner
DM	Data Manager
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
ISF	Investigator Site File
JRO	Joint Research Office
LRN	Lead Research Nurse
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
R&D	Research and Development
RN	Research Nurse
SOP	Standard Operating Procedure
SPR	Specialist Registrar
SSI	Site Specific Information
TMF	Trial Master File
UCLH	University College London Hospitals NHS Foundation Trust

1. BACKGROUND

This Standard Operating Procedure (SOP) defines the responsibilities of the study Principal Investigator (PI) and his/her delegated study staff to ensure the smooth and accurate conduct of research studies, at University College London Hospitals NHS Foundation Trust (UCLH). The PI has overall responsibility for the conduct of his/her clinical trial to ensure the safety of participants and the reliability and robustness of the data generated. In compliance with ICH GCP Section 4.1 (Investigator's Qualifications and Agreements) & ICH GCP E6 R2 Addendum Section 4.2 (Adequate Resources):

- 4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC[1], and/or the regulatory authority(ies).

- 4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational medicinal product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

- 4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

- 4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

- 4.1.5 The investigator should maintain a list of appropriately qualified individuals to whom the investigator has delegated significant trial-related duties and responsibilities.

- 4.2.5 The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

- 4.2.6 If the investigator / institution retains the services of any individual or party to perform trial-related duties and functions, the investigator / institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated, as a result of these activities.

Whilst the PI will retain overall responsibility for the conduct of all trial activities, they will often delegate responsibility for certain trial activity to appropriately qualified and trained staff. The delegation of responsibilities from PI to trial staff must be clearly and consistently defined and documented by using a study site delegation log. The study site delegation log is an essential clinical trial document to define and record the responsibilities of the research team authorised by the PI for the effective delivery of a particular trial. The delegation log is used as evidence to

[1] *In the UK, the IRB/EC is known as the NHS Research Ethics Committees (RECs).*

demonstrate how individuals are assigned to trial tasks appropriate to their education, training and experience, and is a key essential document stored within the TMF/ISF.

2. PURPOSE

The purpose of this SOP is to ensure that members of the UCLH research team understand their key roles and responsibilities for the effective management and conduct of a clinical trial as per trial protocol, study type and sponsor expectations.

3. PROCEDURE

WHO?
The study staff members involved in clinical trials includes, but is not limited to, the following:

- Chief Investigator (CI)
- Principal Investigator (PI)
- Health Care Assistants (Nursing Auxiliary staff) (HCA)
- Co-Investigators (Co-I)
- Specialist Registrars (SpR)
- Lead Research Nurse (LRN)
- Research Nurse (RN)
- Clinical Trials Practitioner (CTP)
- Data Manager (DM)
- Clinical Trials Administrator (CTA)
- Additional Study Staff: Clinicians, Specialist Nurses, Pharmacists, Laboratory staff, Other support staff (e.g. Radiology)

Good Document Practices:

Any changes made to the study delegation log will be documented as per 'Good Document Practice' (detailed below) and a File Note will be created contemporaneously to document the reason for the change. The File Note will be saved in the study's Investigator Site File with the study delegation log.

Good Document Practice: If a correction needs to be made, the original record must still be legible and an accurate record of the trial activities

1. Make a single line through the error
2. Record the correction near the error strike through area
3. Add your initials and date next to the correction
4. State briefly the reason why the correction was made (as per GCP E6 R2).
5. The original entry must still be legible - do not obscure original entries that were made & do not overwrite mistakes.

1	**Responsibilities of the Principal Investigator (PI) /CI** The PI has overall responsibility for the conduct of a clinical trial at a trial site. Within the TMF/ISF, the PI/CI should maintain a study site delegation log of appropriately qualified personnel to whom they have delegated significant	**PI/CI**

	trial-related duties. The PI should ensure that all persons assisting with the trial activities are appropriately qualified, experienced and adequately informed about the protocol, and of their trial-related duties/responsibilities and the IMP (if any). ICH GCP E6 R2 Addendum (effective 14 June 2017), extends the investigator's responsibility beyond ensuring staff training and delegation, to continually supervising and documenting their oversight of all delegated study staff. UCLH PIs are recommended to complete one of the following suggestions to acknowledge their supervisory role of delegated study staff, with evidence detailed within the study subject's medical notes. Documentation of PI acknowledgment must be saved in the trial's Investigator Study Site File: • Quarterly Letter of Acknowledgment: PI to sign a trial-specific acknowledgment letter confirming their supervisory oversight of delegated staff for that quarter. (Repeat quarterly) • Update Study Delegation Log: PI to update and sign/date their listing on the study delegation log task 'Other' with the following statement: 'To continually supervise and document oversight of all delegated study staff, per ICH GCP E6 R2 Addendum.' (Completed once per study) • PI Responsibility Agreement Form: PI to agree, sign and date a PI Responsibility Agreement Form that highlights their key responsibilities as outlined in GCP, together with the following statement: 'I confirm that I will continually supervise and document oversight of all delegated study staff, per ICH GCP E6 R2 Addendum.' (Repeat every 2 years, as per site requirements).	
2	**Site Study Delegation Log** The PI must keep a record of the delegation of clinical trial duties and responsibilities as per the Sponsor's requirements through a Delegation Log (see template enclosed as per Appendix 1, the Sponsor may also provide their own copy). The PI may delegate duties to key study team staff as outlined in their Roles & Responsibilities (as per Appendix 2). The PI must ensure that the delegation log aligns with ALCOA+ principles for data integrity.	**PI**
3	**Signing the Delegation Log** Key study staff members are responsible for completing and signing the study Delegation Log prior to working on the study, ensuring they are delegated tasks and responsibilities appropriately. The PI should review each staff member's tasks and responsibilities and countersign the delegation log as confirmation that the PI is delegating the listed tasks to that particular study team member. The PI's countersignature must be completed prior to a study staff member commencing any trial related activities.	**PI & delegated study staff**

	The study delegation log should be reviewed and updated throughout the life of the study on a continuous basis by the PI and delegated study staff to maintain its accuracy should new study team members start, delegated staff leave or change roles from their current post, etc.	
4	**Evidence of Qualification and Training** In alignment with ICH GCP Section 2.8: Each individual involved in conducting a trial must be qualified by education, training, and experience to perform his or her respective task(s)/duties. All delegated study team staff must provide evidence of education, training and relevant experience. It is the responsibility of the PI and delegated study team staff to ensure the site study Delegation Log is updated with staff changes, maintain records of delegated staff training and maintain study staff CVs & GCP Certificates for the duration of the study (as further evidence of qualifications & training).	**Delegated study staff**
5	**Pre-Study Phase** During the pre-study phase of the clinical trial, the PI & delegated study team responsible for the clinical trial should discuss and agree on the study requirements (with the sponsor, if appropriate), ensuring all necessary procedures and assessments are understood and clearly defined. All protocol requirements will be identified and delegation of responsibilities agreed prior to commencing recruitment.	**PI & delegated study staff**
	Individual trial related duties should be defined, established, agreed and recorded and maintained on the site study Delegation Log.	**PI & delegated study staff**
	As new staff members join the study team, trial related duties and functions should be clearly defined, established, agreed and assigned prior to the individual commencing work on the study.	**PI & delegated study Staff**
	During the R&D trial submission process, the PI acknowledges their study responsibilities by signing the declaration on the trial's IRAS form.	**CI**
	Research Units at UCLH may also require their study PIs to sign other documents to ensure oversight over their respective trials (e.g. 'PI Responsibilities Agreement Form' that serves as a reminder of PI duties and responsibilities - to be re-signed every 2 years as per the site requirements).	**PI**
6	**Open Study Phase** During the open-study phase, the PI is responsible for the medical care and supervision of patients on trial; the study's data integrity and the overall study conduct at the site.	**PI**
	The PI & delegated study staff responsible for the clinical trial must ensure they are observing the study protocol requirements (e.g. informed consent, timely SAE reporting) and adhering to their individual roles & responsibilities, as defined on the study delegation log.	**PI & delegated study staff**

	Any new study team staff members working on the trial are responsible for signing the study Delegation Log with PI countersignature prior to working on the study, to confirm that they have been delegated these tasks appropriately.	**PI & delegated study staff**
	The PI should review each staff member's tasks and countersign the delegation log prior to an individual commencing any trial related activity at the site.	**PI**
	When delegated staff member stops working on a trial, the PI or delegated study staff should add the final working date of that particular staff member to their respective 'Date Finished On Trial' or 'Stop Date' column on the study delegation log.	**PI & delegated study staff**
7	**Study Closure Phase** During the study closure phase, the PI has overall responsibility for the study at the site.	**PI**
	The PI & delegated study staff responsible for the clinical trial should ensure they are observing the study closure requirements as per the study protocol and sponsor close down procedures or UCLH SOP 9 Study Close Down, and adhering to their individual responsibilities, as defined on the study delegation log.	**PI & delegated study staff**
8	**Post-Study Closure Phase** During the post-study close out phase, the PI has overall responsibility for the study at the site.	**PI**
	During the post-study closure phase, the PI & delegated study staff responsible for the clinical trial should ensure they are following the study protocol and local SOPs for Archiving Commercial/Non-Commercial Studies and adhering to their individual responsibilities, as defined on the site study delegation log.	**PI & delegated study staff**

4. IMPLEMENTATION & TRAINING

Staff following this SOP shall confirm they have read and understood the procedures outlined above by completing their relevant departmental training log as a record of acknowledgement.

5. PUBLICATION & COMMUNICATION

This SOP is authorised and published on the JRO website: http://www.ucl.ac.uk/jro. The latest version of the SOP will be made available on the JRO website.

The original fully signed master copy is stored in a designated binder within the JRO and maintained by the JRO Research Quality & Safety Manager (or Research Unit QA Manager if a Departmental SOP).

6. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	Template: Study Delegation Log	JRO Website: http://www.ucl.ac.uk/jro
2.	Guide for Approved Responsibilities of Site Staff Members	JRO Website: http://www.ucl.ac.uk/jro

7. REFERENCES

- ICH GCP E6(R2): https://www.ich.org/page/efficacy-guidelines
- U.K Policy Framework for Health and Social Care Research (V3.2, 10/10/2017 Edition): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UCLH SOP 9: Study Close Down
- JRO Website: http://www.ucl.ac.uk/jro

8. APPENDICES

Appendix 1 – Template: Study Delegation Log
Appendix 2 – Guide for Approved Responsibilities of Site Staff Members