##### **APPENDIX 2: GUIDE FOR APPROVED RESPONSIBILITIES OF SITE STAFF MEMBERS**

**The list below is to serve as a guide of approved trial responsibilities for study staff members covering both CTIMP & non-CTIMP studies.**

**Please note: Additional responsibilities (not listed in each category) may be delegated as per trial protocol, study type and sponsor expectations if staff are appropriately qualified, trained and authorised on the study delegation log by the PI.**

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| **Chief/Principal Investigator** | **Co-Investigator (including Consultants & Clinicians in training)** | **Research Nurse (RN)**  | **Clinical Trials Practitioner (CTP)** | **Data Manager** | **Pharmacist** |
| * Overall responsibility for study at site
* Medical care and supervision of patients
* Delegation of study related duties appropriately
* Continually supervise and document oversight of all delegated study staff, per ICH GCP E6 R2 Addendum
* Ensure all staff delegated to work on trial are:
	+ Qualified by education, training & experience
	+ Thoroughly familiar with study protocol and the investigational product(s)
	+ Aware of, and compliant with GCP and any applicable regulatory requirements pertaining to clinical trial conduct or management
	+ Aware of relevant UCLH/Research Unit SOPs
* Familiarity with Investigator Brochure
* Recruitment Strategy
* Screening of patients and confirmation of eligibility
* Informed Consent
* Completion of Informed Consent Form
* Randomisation
* Administration of study drug
* Collection of trial related blood samples
* Completion and return of eCRFs/ CRFs and providing responses to data queries – overall trial data oversight
* Prescriptions
* Documentation of Adverse Events (AE) and signing AE forms
* Timely Serious Adverse Events (SAE) reporting and signing of SAE forms
* Initiation of and ensuring training is in place for new trial personnel
* Ethics committee approval/communications re: amendments
* Ensuring study patients are aware of who to contact should they experience problems or side effects between clinic visits
* Negotiation and completion of the financial agreement
* Indemnity, compensation and insurance
* Investigational product accountability and monitoring of compliance
* Available for audit, inspections and relevant inspection preparation activities
* Archiving
* Responsible for appropriate and relevant reporting as specified in the study protocol (i.e. to authorities, sponsor, CI etc.)Others, as locally applicable
 | * Screening of patients and confirmation of eligibility
* Medical care of patients
* Informed consent
* Completion of Informed Consent Form
* Randomisation
* Prescriptions
* Administration of study drug
* Investigational product accountability and monitoring of compliance
* Responsible for collection of trial specific blood samples
* Completion and return of eCRFs/CRFs and providing responses to data queries
* Documentation of Adverse Events (AE) and signing AE forms
* Timely Serious Adverse Events (SAE) Reporting and signing of SAE forms
* Ensuring study patients are aware of who to contact should they experience problems or side effects between clinic visits
* Ethics committee obligations
* Available for audit, inspections and relevant inspection preparation activities
* Others, as locally applicable
 | * Assisting PI/Co-Is by providing screening source data for PI/Co-I to determine patient eligibility
* Informed Consent (information giving only, unless protocol and necessary regulatory authority permits the RN to obtain written informed consent in a non-CTIMP study
* Randomisation
* Administration of study drug
* Responsible for collection of trial specific blood samples
* Documentation of Adverse Events (AEs) in source data. Initial documentation of AEs in source data should always be followed by clinician confirmation and signature.
* Completion and return of eCRFs/CRFs and data queries
* Support monitoring visits, audits and inspections
* Preparation of SAE reports for medical input and causality assessment
* Notifying patient’s GP of their involvement in the study
* Organisation of clinic appointments and investigations as per protocol requirements
* Ensuring that the patient is aware of who to contact should they experience problems or side effects between clinic visits
* Appropriately document and seek medical advice when handling patients out of clinic.
* As appropriate, collect study IMP from pharmacy and provide to patient
* Monitoring compliance of oral Investigational Medicinal Products (IMPs)
* Providing advice on symptoms management within scope of nursing role and according to study protocol
* Data entry
* Completion and return of eCRFs/CRFs and data queries
* Support monitoring visits, audits and inspections
* Investigator Site File set up and maintenance
* Maintenance of trial logs and essential documents
* Preparations of paperwork for Ethics committee/HRA/R&D
* General Assistance with co-ordination of trial follow-up procedures
* Shipment of trial related samples
* Archiving
* Others, as locally applicable
 | * Assisting PI/Co-Is by providing screening source data for PI/Co-I to determine patient eligibility
* Informed Consent (information giving only, unless protocol and necessary regulatory authority permits the CTP to obtain written informed consent in a non-CTIMP study
* Randomisation
* Responsible for collection of trial specific blood samples
* Documentation of Adverse Events (AEs) in source data. Initial documentation of AEs in source data should always be followed by clinician confirmation and signature.
* Completion and return of eCRFs/CRFs and data queries
* Support monitoring visits, audits and inspections
* Preparation of SAE reports for medical input and causality assessment
* Notifying patient’s GP of their involvement in the study
* Organisation of clinic appointments and investigations as per protocol requirements
* Ensuring study patients are aware of who to contact should they experience problems or side effects between clinic visits
* Appropriately document and seek medical advice when handling patients out of clinic.
* Monitoring compliance of oral Investigational Medicinal Products (IMPs)
* Data entry
* Completion and return of eCRFs/CRFs and data queries
* Support monitoring visits, audits and inspections
* Investigator Site File set up and maintenance
* Maintenance of trial logs and essential documents
* Preparations of paperwork for Ethics committee/HRA/R&D
* General Assistance with co-ordination of trial follow-up procedures
* Shipment of trial related samples
* Archiving
* Others, as locally applicable
 | * Assisting PI/Co-Is by providing screening source data for PI/Co-I to determine patient eligibility
* Randomisation
* Data entry
* Completion and return of eCRFs/CRFs and data queries
* Support monitoring visits, audits and inspections
* Assist RN/CTP with the preparation of SAE reports , as appropriately delegated
* Investigator Site File set up and maintenance
* Maintenance of trial logs and essential documents
* Preparations of paperwork for Ethics committee/HRA/R&D
* General Assistance with co-ordination of trial follow-up procedures
* Shipment of trial related samples
* Archiving
* Others, as locally applicable
 | * Acknowledge receipt of trial supplies
* Drug accountability and monitoring of compliance
* Dispensing of investigational product to patients
* Complete dispensing log
* Maintain Pharmacy Site File
* Monitor storage of Investigational Product
* Others, as locally applicable
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