	JOB DESCRIPTION					
hVIVO better treatments, faster	Associated Documents	HR017	Master Form Number:	G_0304	Version:	5.0

Job Title:	**Clinical Support Specialist (CSS)**
Division:	hSITE
Department:	Clinical Operations
Grade:	3
Reports to:	Senior Clinical Support Specialist
Location:	London
Date of last JD revision:	10 Sep 2019

Overall Job Purpose

Provide support to the multidisciplinary team in the planning and execution of daily activities including panel screening, study specific screening, Quarantine and follow-up. They will work collaboratively with the nursing team to meet the needs of volunteers and support the delivery of policy and procedures.

All clinical assessments, sample collection and dispatch, and data collection are performed in accordance with current regulatory requirements i.e. ICH-GCP

Key Roles and Responsibilities

- Responsible for performing clinical procedures and daily tasks;
- Involvement in the preparation and planning of daily activities;
- Reflect on own and team activities to identify risks, enhance performance and improve quality of volunteer care;
- Practice in accordance to internal policies, Standard Operating Procedures and Study Protocols.
- Assist with the daily management of the clinical area;
- In Screening, to provide receptionist and administrative duties for arriving volunteers to the screening or follow up visit, ensuring the reception area is staffed always during clinic hours;
- Deal with queries, filing, audit information preparation, database entry and general correspondence, quickly and efficiently;
- ;
- Providing information and correct versioned documentation to volunteers, ensuring these are completed correctly;
- Accurate completion of CRF and other data points as required by the protocol;
- Liaise with relevant stakeholders for the daily schedule of volunteer's visit;
- SUpport new team members in training on the job. of new ancillary staff;
- Monitor work areas and practices to ensure that they are safe, free from hazards and conform to health, safety and security legislation, policies, procedures and guidelines;
- Participate in audit where appropriate
- Administrative duties when designated.

Duties Include

- Adherence to ICH/GCP and best practice always;
- Promote volunteer safety and data integrity in accordance with ICH GCP and other statutory instruments, raising and resolving queries;
- Work effectively with others to clearly define values, direction and policies impacting upon operational delivery

- Prioritise own workload and ensure effective time-management
- Perform study specific assessments within time points as required by approved study protocol such as taking vital signs, ECG's and venepuncture & spirometry. Etc.;
- Screening suitable subjects, including panel screen consenting;
- Ensure accuracy and credibility of data gathered;
- Timely data self-checks and responding to data queries and raising deviations;
- Sample collection and management as per SOP/OI and protocol;
- Liaise with laboratories, internal and external, and assist with the ordering of couriers, requests for sample preparation, etc.;
- Responsible for ensuring REES temperature monitoring is recorded, reported and maintained in accordance with internal SOP's;
- Checking of the emergency equipment as required;
- Ordering and maintenance of consumables;
- Maintenance of equipment and escalation to designated Equipment Leads;
- Escalate concerns or problems identified during daily duties to appropriate senior colleagues within appropriate time frame;
- Promote wellbeing of subjects during their study participation;
- Acting as the volunteer advocate during the study participation;
- Input into process improvements and generating Standard Operating Procedures;
- Ordering Stationary as required;
- Deal with all incoming telephone enquiries and written queries promptly and efficiently.

Administrative tasks (when applicable)

- Where these duties form a significant part of the role, other duties will be reduced to accommodate this. Where they do not, the post-holder may still be required to undertake occasional administrative duties to cover annual leave and other absences;
- Welcoming subjects into the Screening unit for panel screen, study specific screen and follow-up;
- Preparing Study Specific Screening and Panel Screening Packs - Ensuring correct version of documentation;
- Generating appointment lists for daily volunteer visits;
- Responsible for ensuring case notes and other associated documents are complete and accurate, tracked and then filed appropriately in the correct patient/volunteer file, and archiving as required;
- Update hVIVO source data capture with the volunteer screening status;
- Obtaining volunteer demographic/contact/bank details to enable Panel Screening payment generation;
- To maintain hVIVO's TOPS database and raise and answer queries to and from other organizations;
- Responding to any queries appropriately;

This is a non-exhaustive list

Special Requirements

- Employees have a responsibility for ensuring the confidentiality of personal information and company data.
- All employees are bound to comply with all company policies and standard operating procedures and are required to update themselves on a regular basis and attend all mandatory training.
- To keep updated and maintain your CPD including attending internal/external seminars/workshops etc.

Please note:

This job description reflects the core activities of the role and as the company and as the individual in this role develops there will inevitably be changes in the emphasis of duties. It is expected that the job holder will recognise this and adopt a flexible approach to work and be willing to participate in training.

Requirement	Essential	Desirable
Qualifications		
GCSE Grade A-C Maths and English (Or equivalent)	√	
Biological Science degree		√
Immediate Life Support	√	
Hep B Immunisation	√	
Competencies and skills		
Fundamental Clinical Care knowledge		√
Demonstrated critical thinking		√
Demonstrated customer service skills	√	
Ability to listen, clarify, identify solutions and agree actions	√	
Identify opportunities for improvement	√	
Good IT skills (Word and Excel or equivalent)	√	
Effective communication skills	√	
Strong and demonstrated attention to detail	√	
Good knowledge of ICH-GCP and regulatory standards	√	
Ability to manage and prioritise workloads	√	
Willingness to learn additional skills	√	
Ability to work independently and within the Team	√	
Positive and Supportive Team player	√	
Experience		
Experience working within the UK healthcare structure a minimum of 12 months ideally within the hospital setting		√
Previous experience in clinical research environment		√

I have read and understood this job description and understand that my employment and continued success within the organisation is based on my ability to perform in the role as described above.

Employee	
Print Name:	
Signature:	
Date:	

Line Manager	
Print Name:	

Signature:	
Date:	