Frimley Health
NHS Foundation Trust

JOB DESCRIPTION

JOB TITLE: Clinical Research Nurse/Practitioner

PAY BAND: Band 6

DEPARTMENT: Research & Development

RESPONSIBLE TO: Senior Research Nurse

DATE: Month Year

PURPOSE OF JOB:

The purpose of the post is to increase the number of patients participating in clinical trials, at Frimley Health NHS Foundation Trust. As a clinical research nurse/practitioner, you will be responsible for assessing and managing the care pathways for patients and carers participating in clinical trials. This will include the recruitment, education and monitoring of trial patients and the collection and documentation of accurate data.

The post holder will work collaboratively with KSS CRN, the senior research nurse, lead research nurse, operations manager and the Associate Director for Research and the existing clinical trials team and multi-disciplinary teams (MDTs). The post holder will also work collaboratively with the clinical trials team and the wider MDT in the management of your own caseload of clinical trial studies and patients. The role involves using an in-depth knowledge of trial protocols and their application in practice, research methods and in-depth working knowledge of local, national and international research regulations.

KEY TASKS & RESPONSIBILITIES:

Clinical Responsibilities

- Work autonomously and assist in the management of a caseload of clinical trial patients whilst working as part of the MDT. Maintain effective communication with patients, carers and professionals to ensure high quality service delivery
- Identify suitable patients for entry into clinical trials by attending clinics (screening notes) and relevant MDT meetings
- Maintain accurate documentation of patient events in the medical notes
- Ensure trial consent protocols are adhered to
- Demonstrate a comprehensive understanding of treatment options, treatment side effects and disease processes to support informed treatment choice for patients
- Provide ongoing information, education and support to patients (and their significant others) and all levels of staff regarding clinical trials and specific trial treatments
- Take and assist in the consent of patients and randomisation of patients to treatment arms

- Ensure that trial specific investigations are undertaken as required by the trial protocol and obtain results in order to establish eligibility and safety to enter the trial
- Ensure the safe administration of treatments and drugs that are given within the context of a clinical trial
- Monitor treatment toxicity/side effects and initiate changes to treatment or treatment cessation as required by trial protocols
- Report and record adverse events which occur whilst patients are under trial therapy to the trial co-ordinator/Principal Investigator and relevant local and regulatory authorities
- Provide continuity of care to patients and their carers throughout the trial programme. Provide specific advice and psychological support as appropriate. Refer to other specialists as required to ensure optimum patient care.
- Act as a primary contact point for the trial participant
- Maintain accurate patient trial documentation, complete Case Report Forms, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes.
- Perform phlebotomy, blood and urine spinning as required by trial protocols, ensure the safe handling, storage and transportation of samples

Research

- Work collaboratively with KSS CRN, the clinical research senior team, the existing clinical trials team, MDTs and other professionals to assist in maintaining and developing a UKCRN clinical trials service at Frimley Health NHS Foundation Trust Hospital
- Implement and adhere to the principles of the International Conference of Harmonisation and Good Clinical Practice (ICH GCP), research governance standards and UK Clinical Trial Regulations where appropriate.

- Support the identification of suitable new UKCRN trials for the Frimley Health NHS Hospital Trust research and development (R & D) portfolio

- Support the set up and management of UKCRN portfolio and commercial trials

- Identify and screen for potential research participants.

- Identify strategies for the recruitment of patients into trials, ascertain barriers to recruitment and implement action as required

- Facilitate the informed consent process by ensuring the following:

- All informed consent procedures adhere to the trail protocol and ethics approval
- The patient (and significant others) fully understands the nature of the clinical trial
- The patient is aware that entry into the trial is voluntary and they can withdraw at any point without prejudice
- The patient is aware of any extra procedures required by the trial
- The consent form is completed accurately and filed as required

- Provide support to UKCRN hosted clinical trials across specialties where necessary to ensure clinical and research governance patient oversight

- Ensure that data is accurately collected and appropriately stored into databases. Forward to trial co-ordinating centres in a timely manner as necessary
- Undertake audit, as required by the R&D department, of studies at Frimley Health NHS Hospital Trust

- Assist clinical research associates monitoring allocated studies with data verification and queries.

- Ensure that follow up visits for research participants are conducted according to study protocol.

- Act as a role model for excellence in the research process

Management

- Promote and support the continued development of the clinical trials service at Frimley Health NHS Hospital Trust

- Support the development, continued growth and maintenance of the nursing research service and assist in the review and audit annually

- Support the production of the annual report and relevant reviews for the Trust and the KSS CRN as requested

- Liaise with members of the MDT i.e. pharmacists, radiologists, pathologists to ensure safe and smooth running of trials

- Support the co-ordination, preparation and submission of research to the relevant NHS research ethics and R&D committees for approval. Manage amendments to allocated trials by preparing and providing relevant documentation for local R&D submission.

- Ensure that all research governance approvals (both locally and externally) are in place prior to commencing the trial

- Contribute to the development of clinical and research policies, procedures and Trust standard operating procedures
- Input and maintain data recorded on the EDGE project management system used at the Trust
- Ensure that clinical trial recruitment records are accurately maintained

- Ensure that clinical trials are effectively archived as required
- Manage and prioritise time effectively
- Be aware of the Trust's complaints procedure and role of the Trust's Patient Advice and Liaison Service. Prepare accurate and timely statements in response to incidents and complaints
- Undertake regular individual performance review in conjunction with line management. Agree personal professional development plans in line with service objectives and wider clinical research and DOH&SC initiatives
- Assist in the preparation of costings for clinical trials
- Attend relevant specialist nurse forums at Trust level as required
- Be prepared to travel off-site as necessary, to, for example and not limited to, attend meetings, clinics, patient recruitment

Education & Development

- Act as a resource for colleagues and patients in relation to clinical trials. Ensure all relevant health care professionals are educated and supported as required enabling them to care for clinical trial patients

- •Participate in the identification of training and education needs of Trust staff and support the planning, organisation and presentation of educational programmes relating to research

- Attend trial investigator/research nurse meetings and conferences when required

- Maintain links with other clinical trial nurses and clinical nurse specialists across the network to share knowledge and to provide mutual support

- Maintain awareness of current advances in relevant treatments, research and nursing practice and use this knowledge to maintain high standards of care for patients

- Disseminate research by assisting in the preparation of posters/research papers for meetings, conferences and publications

- Attend relevant MDTs, working groups and business meetings to disseminate information about performance and to speak about potential new clinical trials and service development as required

- Assist in the development of patient Information and information to General Practitioners for patients participating in clinical trials

- Continually update and maintain own professional development in research through attendance at local and national training programmes and other relevant education and training programmes

- Disseminate findings from own professional development through the use of written reports, presentations and the implementation of educational initiatives

- Maintain an up-to-date knowledge of research related articles particularly

Professional

- Work within the NMC Scope of Professional Practice and Code of Conduct
- Attend mandatory lectures and training as set out in the Trust guidelines

- Act in accordance with local policies and procedures laid down by Frimley Health NHS Hospital Trust

- Be aware of the Trust's complaints procedure and role of the PALS Team

This job description is an indication of the type and range of tasks that are expected of the post holder, and other duties may be required, in line with the role and the banding. It will be reviewed and amended from time to time in consultation with the post holder to take account of changing organisational need.

This job description should be read in conjunction with the non-supervisory JD Addendum, available at: https://www.fhft.nhs.uk/media/2754/jd-addendum-non-supervisory.pdf

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PERSON SPECIFICATION

JOB TITLE: Clinical Research Nurse/Practitioner

PAY BAND: Band 6

DEPARTMENT: Research and Development

CRITERIA	Essential	Desirable
Qualifications	• NMC registration • Degree or degree level qualification • Excellent computer skills (Word, Excel, email, Internet	• ENB 998/Mentor PREP or City and Guilds 730 • Evidence of continuous professional development
Experience	• Training and education of nurses and other health care professionals • Multi-professional working utilising research evidence • Recent use of audit • Analytical and assessment skill	• Commitment to service development
Skills & Knowledge	• Evidence of leadership skills • Demonstrates good communication and presentation skills, both verbal and written • Ability to work independently, but equally well as a team member • • Commitment to achieving the objectives of local Research and Development and within the wider context of the CRN. • Good time management and organisational skills • Patient education/counselling skills • ICH GCP training or be prepared to do	• Report writing • Knowledge of ICH Good Clinical Practice Guidelines for clinical trials • Project management experience
Special Requirements	• Willingness to acquire and develop additional skills and qualifications necessary to carry out the role • Ability to travel between sites, including with equipment and documents. E.g. car driver with full driving licence	•

Values & Behaviours	We will expect your values and behaviours to mirror those of the Trust, available at: https://www.fhft.nhs.uk/about-us/our-values/