University Hospitals of Leicester NHS Trust

Job Description

Job Title:	ITU Associate Clinical Research Practitioner
Band:	NHS Agenda for Change Band 4
Base:	NIHR Biomedical Research Centre- Respiratory and Infection Theme, Glenfield Hospital
Reports to:	Clinical Research Manager Senior Research Nurse/Team Leader
Accountable to:	Director – NIHR Leicester Biomedical Research center- Respiratory Theme Head of Research (Nursing & Midwifery)

Job Summary	We are seeking an experience clinical associate research practitioner to join Research and Innovation (R&I) department at University Hospitals of Leicester NHS Trust as an ITU clinical associate research practitioner at Glenfield hospital as part of the NIHR Biomedical Research Centre – Respiratory and infection Theme. The post holder will support current portfolio research staff in ensuring the completeness, accuracy and consistency of the data in order to meet standards expected for reporting to regulatory bodies. The individual will provide clinical support to patients in clinical trials; such as taking samples, performing tests and physical measurements in accordance with the clinical trial protocol, and Good Clinical Practice. A key responsibility of the role will be to support research within the ITU Research Team at Glenfield hospital as part NIHR Biomedical Research Centre- Respiratory and infection theme and take responsibility for the co-ordination and facilitation of concurrent research studies. The post holder will ensure compliance within UHL Trust policies on data protection, confidentiality and security. The role will provide clinical research assistant support to the ITU Team conducting research at UHL.

	The post holder will provide the highest standards of patient care in line with research protocols and will ensure that such research safeguards the well-being of the patients and is conducted within ICH Good Clinical Practice guidelines for research. The post holder will work alongside Principle Investigators and the research team to assist in the delivery of a high quality research service and ensure the highest standard of care is delivered to research subjects and, where relevant to their families, in partnership with all members of the multi professional and research teams. The post holder should be adaptable, flexible and show initiative. In addition they need to show good communication skills, be able to liaise with all levels of staff, demonstrate good organisational skills and attention to detail, have good time management skills and be flexible as the working hours may not be fixed. The post-holder may be required to work in other research areas across UHL if service needs arise. This post will predominantly be a Monday - Friday office hours however may need flexibility depending on the study requirements.

KEY WORKING RELATIONSHIPS

Clinicians
Principle Investigators
Research Scientists
BRC Theme Clinical Manager
BRC Theme Operations Manager
Research Nurses / Research Officers / Research Assistants
Research Champions
Acute care wards and teams associated with these wards
Research Participants / Patients / Carers
Other Clinical/Research Groups
Support Services

KEY RESULT AREAS

KEY AREAS

1) Research Trial Set Up and Initiation

2) Assist with the acquisition and distribution of relevant trial documentation/equipment.

3) Provide assistance in the preparation and submission of documentation for Ethical Approval and the NIHR CSP and EDGE process

4) To establish trial site files for each trial in accordance with ICH-GCP and research governance.

5) Collection of patient data from medical notes and completion of case record forms (CRF's) and to liaise with clinical trial co-ordinators, research nurses and investigators to ensure accurate data collection

6) To transcribe/export data from medical records (paper or electronic) to CRF's (paper or electronic) as required by the study protocol

7) Facilitate the secure filing and storage of study documentation in accordance with ICH- GCP and Research Governance and conduct quality assurance of documentation

8) Organise and prepare for visits by trial monitors as required by the study protocol

9) Take responsibility for liaising with clinical trials units/study sponsors regarding data queries and for checking and resolving data queries

10) To evaluate patient eligibility, in liaison with other appropriate health care professionals for clinical trial entry, involving coordination of pre study tests, obtaining results and arranging appropriate appointments as per clinical trial protocols.

11) Have a solid understanding of the application of ICH GCP Guidelines, the EU Directive on Clinical Research and Research Governance

12) To ensure patients / carers are provided with written information relevant to the research study and are given the opportunity to discuss the research study or clinical trial adequately at the outset and during the course of the research or clinical trial in which they are being asked to participate (i.e. informed consent)

13) Attend and support patients in the clinical environment for monitoring, assessment and follow up as part of research projects

14) Where appropriate, to take consent from patients/participants to enter research studies

15) To take relevant patient samples for clinical trials; such as blood samples, to centrifuge and separate serum, package and dispatch as per defined protocols, where appropriate

16) Observe patients and monitor treatment toxicity/side effects; escalating findings accordingly

17) Maintain accurate patient trial documentation, complete Case Record Forms, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes

18) Ensure safety data is reported to required SOPs and study protocols, and reports sent in a timely manner

19) To ensure safe and appropriate storage of specimens in accordance with the trial protocol and in conjunction with specialist teams

20) To record and report any adverse and serious adverse events according to trial protocol and local procedure.

21) Contribute to effective communications within the CRN East Midlands, including preparation and delivery of regular presentations and reports.

22) Establish and maintain effective working relationships with all relevant organisations and individuals, including member NHS Trusts, other NIHR Clinical research networks and other providers of NHS services within the CRN, Clinical Trials Units, Industry, and NHS commissioners.

23) As a new post holder, training will be provided for the key aspects of this role, and a period of induction identified, however, the post holder will be expected to take advantage of opportunities to upgrade their skills and to attend meetings and workshops to enhance their knowledge.

R&I DIRECTORATE

1. Identify personal educational needs associated with participation in current clinical trials and ensure these are effectively communicated to the Research Manager. Participates in the development of an agreed personal development plan to meet identified needs.

2. Ensure safe standards of practice through identification of areas of risk associated with participation in clinical trials. Ensure clinical trial protocols and appropriate professional guidelines are adhered to.

3. Participate in the implementation of research practice standards.

4. Responsible for remaining adequately informed of clinical trials, R&I activity and the Trust by attendance at team brief and using other appropriate forms of communication.

5. To undertake mandatory training as required by the individual Trusts and additional clinical, research and IT training as required by the research studies

6. Work to SOP's, applicable regulatory requirements and laws as per required and applicable to each research study, department and Trust

7. Manages a personal caseload of clinical trials and patients independently with minimal supervision/mentoring from Principle Investigators/senior research nurses/team leaders.

8. To ensure relevant approvals are in place prior to commencing each trial.

9. To ensure all work is undertaken in line with the research protocol, ICH-GCP and Research Governance guidelines.

10. To act as one of the primary points of contact for clinical trials patients/ parents.

11. To educate other staff as to the responsibilities of the role and function of the research team and disseminate information on specific studies.

12. Observe patients and monitor treatment/toxicity side effects; escalating findings accordingly.

13. To maintain Professional Accountability for nursing research practice at all times

14. Identifies, screens and recruits patients for the clinical trial using agreed protocols in accordance with ICH-GCP and Research Governance

15. Provides education and support for patients in research trials

16. Work with the lead clinician to evaluate clinical trial proposals, identifying potential patient populations and evaluating cost implications of the trial.

17. Work with the Ethics and Governance team to ensure all clinical trial documentation has appropriate ethical committee and Trust approval providing feedback to the lead clinician and research directorate.

18. Participate in set-up/initiation/monitoring visits, site audits and study close-down meetings carried out by sponsoring organisations and regulatory authorities.

19. Provide on-going audit reports as required by the trial protocols and Research & Innovation department/ethics committee.

20. Responsible for resolving data queries raised by sponsoring organisations.

21. Demonstrates commitment to the role of patient advocate for patients and families considering or participating in clinical trials.

22. To provide mentorship and supervision for other research professionals and staff within and outside the department.

23. Act as a resource for ward based nurses wishing to undertake research once competencies have been achieved.

24. Responsible for assisting with the completion of study costing templates along with assisting with invoicing and the recovery of income for commercial research as per financial contract agreement.

25. Act as a role model for excellence in research.

26. Management and co-ordination of specified trials and take responsibility for :
    - Organisation of any necessary tests and investigations as detailed within the protocol.
    - Sample preparation (e.g. blood, urine, tissue and faecal samples): retrieval, centrifuging, pipetting, slide making and preparation for storage, liaising with the hospital and external laboratories when appropriate.

- Maintaining logs of stored samples and freezer temperatures.
- Maintaining adequate stock levels of sample kits.
- Organising the logistical aspects of diagnostic specimens, packaging, and shipment, including handling of dry ice.
- Organising and completing follow up assessments including toxicity, Quality of Life assessments and telephone assessments.
- Resolving data queries raised by sponsoring organisations.
- Archiving all study related material including patient's notes after study closure.
- Reporting and submitting of Serious Adverse Events (SAEs) from this site within stipulated timeframes to sponsor organisations and the Research and Innovation Office.
- Tracking Serious Unexpected Event reporting
- Maintaining and updating study specific site files.
- Notifying General Practitioners of their patient's involvement in a clinical trial.

As a new post holder, training will be provided for the key aspects of this role, and a period of induction identified, however, the post holder will be expected to take advantage of opportunities to upgrade their skills and to attend meetings and workshops to enhance their knowledge.

OTHER:

Terms and conditions:
NHS Agenda for Change Terms and Conditions apply. Any other particular conditions are listed here:

(Agenda for Change) Working Conditions:

Physical effort: Working both desk and clinically across a range of environments; some light lifting and movement of equipment (e.g. files) and travelling.

Mental effort: There will be occasional requirement to carry out formal trainee/student assessments and carry out calculations. Frequent requirement to carry out clinical care interventions, operate equipment, attend meetings, check documents.

In depth mental attention, combined with proactive engagement with the subject will be required when working in a clinical setting. Concentrating continuously for long periods is required when working at a desk. Work pattern can be unpredictable, and work is likely to be frequently interrupted to deal with queries.

Emotional effort: There will be occasional requirements to process news of highly distressing vents, directly giving unwelcome news to patients/parents, directly or indirectly caring for terminally ill or very unwell patients, and directly communicating life changing events.

The post holder may have to deal with complex research issues involving difficult conversations with patients, parents, clinicians, researchers, other R&I staff and will need to do this tactfully and tenaciously.

Working conditions: There will be occasional exposure to body fluids, contaminated equipment and work areas, dangerous chemicals and substances. There will use of a computer for prolonged periods on most days.

GENERAL DUTIES

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https://www.leicestershospitals.nhs.uk/aboutus/work-for-us/

Person Specification

Post: Assistant/Associate Clinical Research Practitioner
Band: 4

Criteria	Essential	Desirable	Stage Measured at A – application I – Interview T – Test
Commitment to Trust Values and Behaviours	Must be able to demonstrate behaviours consistent with the Trust's Values and Behaviours		Interview
Training & Qualifications	Minimum Grade C or above GCSE/Equivalent to include English and Maths Evidence of on-going professional development Willing to undertake any necessary training relevant to the post	Evidence of specialist training or willingness to undertake additional specialist/academic training	Application form
Experience	Experience in acute care/ITU/Theatres specialty or experience of the clinical care of patients enrolled in research studies		Application form

Communication and relationship skills	Proven verbal communication skills with different staff groups Ability to educate and support colleagues, patients and carers Ability to work independently and/or as part of a team		Application form and interview
Analytical and Judgement skills	Ability to evaluate patient eligibility for entry into clinical trials against defined protocols Ability to problem solve. Good IT Skills, particularly in the use of Web applications and MS Office /database skills		Application form and interview
Skills	Clinical skills including vital signs monitoring.	Extended clinical skills such as Venepuncture, cannulation, spirometry or other bespoke research assessments or willingness to undertake full training	Application form and interview

Planning and organisation skills	Ability to work independently and as part of a small specialist team Able to demonstrate planning and organisational skills Ability to manage time effectively, prioritise work and to deliver results consistently to deadlines Attention to detail Ability to manage time effectively,	Awareness/understanding of current national systems and structures for the approval, management and monitoring of clinical research in the NHS Understanding of research design and methodology	Application form and interview
Equality, Diversity and Inclusion	Able to demonstrate a commitment and understanding of the importance of treating all individuals with dignity and respect appropriate to their individual needs.		Application form and interview
Other requirements specific to the role	Highly motivated Flexible approach to working and a desire to develop knowledge. Assertive, confident and diplomatic Demonstrates enthusiasm		Interview

	Professional manner		