Job Description

York and Scarborough Teaching Hospitals NHS Foundation Trust

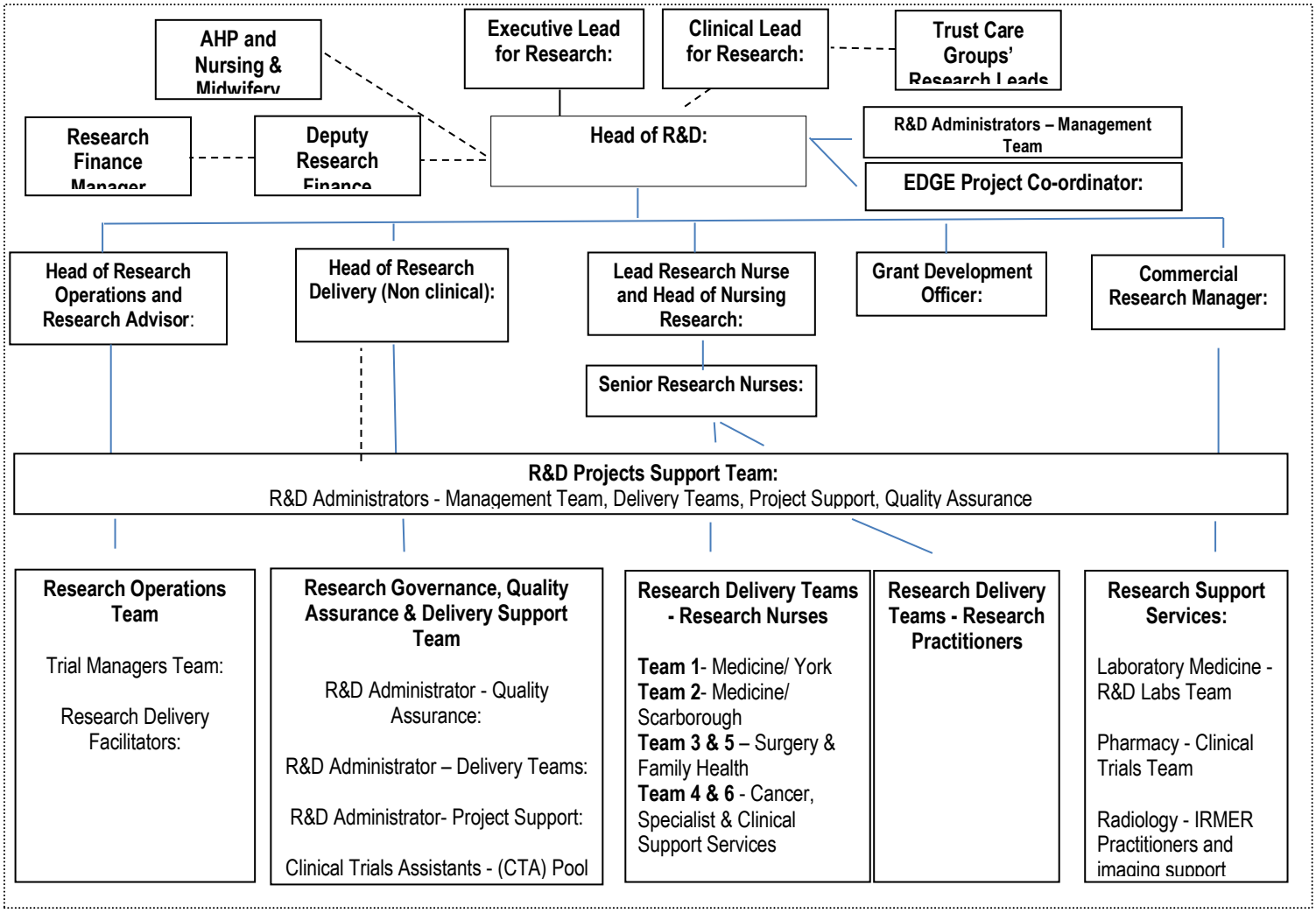
Job Title:	Research Nurse		
Band:	6		
Department:	Research & Development		
Care Group:	Workforce and Organisational Development		
Reports To:	Senior Research Nurses		
Accountable To:	Lead Research Nurse		
Professionally Accountable To:	York and Scarborough Teaching Hospital Lead Research Nurse Lead Clinicians		
Responsible For:			
Main Base/ Site:	York Hospital		
Contract Status:	☐ Permanent	☒ Fixed Term	☐ Other:
AfC Reference Number:			

JOB SUMMARY

The purpose of the role is to meet the needs of those who use the York and Scarborough Teaching Hospital Clinical Trials Service. To carry out research as part of a formal research programme and where required support our local academic partner organisations with trials, including early phase/healthy volunteer trials. The post holder is responsible for management of a defined caseload of patients participating in clinical trials within this specialist area and carries continuing responsibility for assessment of care needs of clinical trial participants and for providing them with high quality care that is timely and protocol-driven. The post holder will provide specialist nursing care and advice to patients on all aspects of their involvement in clinical trials, including identification, advising and proper reporting of any adverse events. The post holder will contribute to development of the speciality service to clinical trial participants and ensure cost effective use of resources.

In all respects the post holder must act in accordance with the Nursing and Midwifery Code of Conduct, the Research Governance Framework for Health and Social Care and the appropriate quality standards for each trial (e.g. International Conference on Harmonisation of Good Clinical Practice in Clinical Trials (ICH-GCP).

ORGANISATIONAL CHART



RESPONSIBILITIES

To manage own caseload of several clinical trials with various numbers of patients participating, including the following key tasks:

1. Manage a portfolio of clinical trials, working closely with the trial's local Principal Investigator to provide the key point of contact for that trial within the Trust;
2. Become familiar with the protocols for all trials in the portfolio for which the post holder is responsible;
3. Identify patients who may be suitable for clinical trials in the portfolio, liaising with clinicians and attending clinical team meetings to promote research participation and remind clinical team members about the requirements for trials that may be of value to their patients.
4. Work with the local Principal Investigator to recruit patients to trials;
5. Give information to patients considering trial participation, answer their questions and refer to the Principal Investigator where required.
6. Ensure that all consent procedures are carried out in strict accordance with the relevant trial protocol.
7. Undertake clinical procedures with trial participants as appropriate, including taking bloods and administering intravenous medication.
8. Obtain clinical specimens from participants and organize their safe and timely delivery to the appropriate laboratory.

9. Liaise with clinical staff to ensure the timely administration of investigation, treatment and follow-up required for trials.
10. Contribute to trial pharmacovigilance by being aware of the categories of research – related adverse event and ensuring prompt recording and reporting both within the Trust and to regulatory authorities as the particular nature of the event requires.
11. Complete case report forms and all trial documentation accurately and promptly.
12. Maintain Site files and ensure they are up to date at all times.
13. Act as a primary contact for participants in designated trials.
14. Maintain contact with participants during investigations, treatment and follow-up, including home visits where appropriate; provide advice and emotional support as required and ensure participants are kept fully informed and are able to take part in decisions about their care within the trial.
15. Use software for data inputting, data management and reporting as required.
16. Work to the requirements of trial protocols, the Good Clinical Practice Guidelines applicable to the particular Study (e.g. ICH/GCP) and the Research Policy for Health and Social Care Research 2017. Deal with ethics and research governance approval processes as required and ensure that notices of any amendments are given promptly.
17. Assist in monitoring visits conducted by Sponsors or their nominated representatives.
18. Participate in inspections by the Medicines and Healthcare Products Regulatory Agency as required, ensuring all trial documentation is in good order, answering Inspectors' questions about trial conduct, contributing to response made to any findings and ensuring appropriate modifications to procedures are made in a timely fashion, particularly in relation to 'critical' or 'major' findings.
19. Carry out any other trial-related duties within the post holder's qualifications and competence as delegated by the Senior Research Nurse or the relevant trial's Principal Investigator.
20. Promote the work of Research within the Trust and contribute to development of the Oncology portfolio of trials.
21. To assist with medical emergencies for all trial participants including healthy volunteers.

KEY RELATIONSHIPS

- Research Nurses
- R&D staff in York and Scarborough
- Staff in clinical areas
- External sponsors and Pharmaceutical Companies

KNOWLEDGE AND SKILLS

1. Communication and Relationship Skills

- Ability to interact directly with patients who may be recently diagnosed with serious or terminal illness, and their family members, to answer questions about the condition and about clinical trial participation.
- Liaise with consultants, other medical staff and health professionals to ensure satisfactory communication with patients and seamless delivery of care.
- Receive complex information about patients' conditions from Consultants and others involved in the care of trial participants.
- Receive complex information about design and conduct of specific clinical trials from Chief Investigators and national or regional Network co-ordination staff.
- Communicate complex information, which may sometimes be highly sensitive, to patients participating in clinical trials, ensuring that they are fully informed and able to participate in decisions about their own care.

- Maintain accurate clinical, research and other records using the Trust's documentation or clinical trial site files and data collection instruments.
- Participate in MHRA inspections; interact with Inspectors, answering their questions, contributing to preparation of responses in writing.

2. Knowledge, Training and Experience

- Registered Nurse.
- Diploma level education or equivalent
- The post holder will undertake such training as may be required by the Trust or the relevant Research Network Co-ordinating Centre (if any) for the better performance of the job, and such general training as may be required in connection with employment by York and Scarborough Hospitals NHS Foundation Trust.
- Professional clinical knowledge of nursing patients or patient care, acquired through at least 2 years post registration experience.

3. Analytical Skills

- Ability to make judgements about a range of clinical issues or complex patient conditions.
- Ability to make judgements about best way to achieve complete treatment plan and data collection in line with research protocols.
- Ability to identify patients who may be eligible for trials and evaluate their eligibility in relation to complex research protocols, referring to other professionals as necessary.
- Ability to deal with telephone enquiries from staff, patients and carers, using judgement to respond or refer to appropriate personnel.

4. Planning and Organisational Skills

- Ability to plan and co-ordinate research activities including activities carried out by other members of the multidisciplinary team.
- Ability to ensure all trial data are collected within specified time constraints.
- Ability to co-ordinate study tests, obtaining results (e.g. X-Ray reports) and co-ordinating test activities as per clinical trial protocols.

5. Physical Skills

- Ability to deliver appropriate treatment as required by clinical trial protocols including administration of intravenous medication and other clinical procedures where dexterity and accuracy are required.
- Standard keyboard skills.

6. Responsibilities for Patient/ Client Care

- The post holder is responsible and accountable for their own practice in line with Trust Infection Prevention and Control policies that reflect evidence, best practice and legislative requirements.
- The post holder will have the appropriate level of child protection knowledge, skills and practice required for the post and be aware of and comply with the Trust's child protection policies and procedures.
- Assess, plan, implement and evaluate care provided for patients under clinical trial protocols, using specialist clinical knowledge and skills, advising patients and their family members as appropriate.
- Organise own clinical workload.

7. Responsibilities for Policy and Service Development

- Ability to disseminate research results appropriately to participants and staff involved in project.
- Ability to support the development and integration of research pathways into clinical pathways.

8. Responsibilities for Financial and Physical Resources

- The post holder will support the Trust's internal audit service during regular reviews of financial and other systems across the organisation. The post holder will assist audit in these reviews and will provide information as required and without undue delay.
- May be required to make minor purchases in relation to role and equipment needed/used.

9. Responsibilities for Staff/ HR/ Leadership/ Training

- Supervise the learning and development of junior members of staff.
- Supervise and support research tasks by clinical staff.

10. Responsibilities for Information Resources

- The post holder will maintain the security of sensitive personal and other confidential information and will apply all relevant Information Governance policies reliably to working practice. Additionally they will be expected to follow secure operating procedures for handling information in all formats, including verbal, written and that held electronically.
- Ability to collect and collate trial data and complete trial documentation, maintaining all Study Site files to ICH-GCP standards and in a condition that would pass inspection by the Medicines and Healthcare Products Regulatory Agency;
- Ability to use advanced software to collect data, create reports and manage data.

11. Responsibilities for Research and Development

- Regularly undertakes research and development as a requirement of the job.
- Ability to facilitate a high quality clinical trials service.
- Ability to meet the needs of staff, patients and carers involved in the research.

12. Freedom to Act

- Organise own research workload, seeing patient participants as required to carry out stages of the research process.
- Significant discretion to work independently; without direct supervision.
- Refer patients as appropriate to other members of the multi-disciplinary team.
- Act as the key worker in relation to clinical trial participation and patients' dealings with the multidisciplinary team.
- Be accountable for own professional actions under Nursing and Midwifery Code of Conduct.

EFFORT AND ENVIRONMENT

13. Physical Effort

- Ability to carry out the following tasks involving frequent moderate physical effort for short periods:
- Push or lift equipment and study materials, which can be substantial;
- Move or manoeuvre patients.

14. Mental Effort

- Ability to concentrate frequently for patient assessment, treatment and research activities.

15. Emotional Effort

- Ability to cope with frequent exposure to distressing or emotional circumstances – trial participants will often be patients recently diagnosed with serious, sometimes terminal illness, or about to embark on a trial because other treatment options have failed.

16. Working Conditions

- Occasional need to deal with unpleasant conditions, occasional highly unpleasant conditions (bodily fluids, odours).

KEY VALUES

The Trust would expect all employees to demonstrate our values as part of their day to day working lives:

- We are **kind**
- We are **open**
- We pursue **excellence**

These values are underpinned by behaviours:

We are **kind**, this means we:
- **Respect** and value each other;
- Treat each other **fairly**;
- Are **helpful** and seek help when we need it.

We are **open**, this means we:
- **Listen**, making sure we truly understand the point of view of others;
- Work **collaboratively**, to deliver the best possible outcomes;
- Are **inclusive**, demonstrating everyone's voice matters.

We pursue **excellence**, this means we:
- Are **professional** and take pride in our work, always seeking to do our best;
- Demonstrate high **integrity**, always seeking to do the right thing;
- Are **ambitious**, we suggest new ideas and find ways to take them forward, and we support others to do the same.

STANDARD GENERIC ITEMS:

The post holder will uphold and support these values in accordance with the Behavioural Framework. To this end, in our goal to promote and embed equality and diversity throughout the organisation, the post holder will ensure that everyone is treated as an individual, with dignity and respect.

In addition to observing the departmental rules and procedures, which all staff are required to observe and follow, the post holder will also be required to follow the Trust's general policies and procedures that apply to the employment relationship. Whilst the Trust recognises specific responsibilities fall upon management, it is also the duty of the post holder to accept personal responsibility for the practical application of these policies, procedures and standards. The post holder should familiarise themselves with these, and ensure they have an understanding of them, and adhere to them.

The Trust has a No Smoking Policy. All its premises are considered as non-smoking zones.

In order to ensure the Trust's ability to respond to changes in the needs of the service, the Trust may make changes on a temporary or permanent basis, that are deemed reasonable in the circumstances, to the duties and responsibilities outlined in the job description. Any changes will be made with reasonable notice, taking into account the circumstances of the Trust and the post-holder.

This job description is not meant to be exhaustive. It describes the main duties and responsibilities of the post. It may be subject to change as the organisation and services develop and wherever possible change will follow a consultation with the post holder.

JOB AGREEMENT:

Job Holder *(PRINT NAME)*	
Job Holder *(SIGNATURE)*	
Date	

Recruiting Manager *(PRINT NAME)*	
Recruiting Manager *(SIGNATURE)*	
Date	

Person Specification

York and Scarborough Teaching Hospitals NHS Foundation Trust

Research Nurse

Criteria	Essential	Desirable
Education, Qualifications and Training	• Registered Nurse. • Diploma level education or equivalent. • Stroke Experience • Training in ICH-GCP clinical trial standards and the detailed trial-specific rules it provides for administration and record keeping – if formal training not already undertaken, willingness to be sent on training course at start of the job.	• Working towards degree or equivalent.
Experience and Knowledge Required	• Professional clinical knowledge of nursing patients or patient care, acquired through at least 2 years post registration experience. • Understanding of the local and National nursing agenda. • Understanding of relevant National Service Frameworks / National guidance. • Understanding of research based practice. • Evidence of continued professional development.	• Post registration qualification in Speciality.
Skills and Attributes	• Ability to interact directly with patients who may be recently diagnosed with serious or terminal illness and their family members, to answer questions about the condition and about clinical trial participation. • Liaise with consultants, other medical staff and health professionals to ensure satisfactory communication with patients and seamless delivery of care. • Receive complex information about patients' conditions from Consultants and others involved in the care of trial participants. • Receive complex information about design and conduct of specific clinical trials from Chief	

	Investigators and national or regional Network co-ordination staff. • Communicate complex information, which may sometimes be highly sensitive, to patients participating in clinical trials, ensuring that they are fully informed and able to participate in decisions about their own care. • Maintain accurate clinical, research and other records using the Trust's documentation or clinical trial site files and data collection instruments. • Participate in MHRA inspections; interact with Inspectors, answering their questions, contributing to preparation of responses in writing.	
Aptitude and Personal Qualities	• Ability to make judgements about a range of clinical issues or complex patient conditions. • Ability to make judgements about best way to achieve complete treatment plan and data collection in line with research protocols. • Ability to identify patients who may be eligible for trials and evaluate their eligibility in relation to complex research protocols, referring to other professionals as necessary. • Ability to deal with telephone enquiries from staff, patients and carers, using judgement to respond or refer to appropriate personnel. • Ability to plan and co-ordinate research activities including activities carried out by other members of the multidisciplinary team. • Ability to ensure all trial data are collected within specified time constraints. • Ability to co-ordinate study tests, obtaining results (e.g. X-Ray reports) and co-ordinating test activities as per clinical trial protocols.	
Values & Behaviours	Ability to demonstrate our organisational values and behaviours: • We are **Kind.** • We are **Open.** • We pursue **Excellence.**	