Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015



Job Description

Job Group:	Nursing & Midwifery
Job Title:	Research Nurse/Practitioner
Existing Grade:	5
Care Group:	Research & Development
Service Line:	Research and Development Summary
Department:	Research & Development
Location:	Bircham Park Offices, Level 2, MSCP,1, Roscoff Rise,
	Derriford, Plymouth, PL6 8BQ
Appraiser:	To be confirmed
Accountable to:	Team Leader
Position Number:	
Date:	

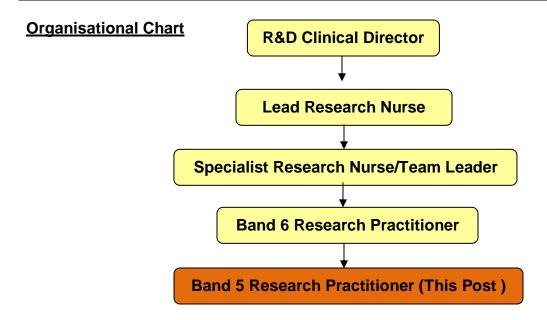
Job Purpose:

The Research Nurse / Practitioner will work as part of the clinical research team to support the safe conduct of research in in accordance with the Research Governance Framework and Good Clinical Practice guidelines and provide assurance that the rights, safety and well-being of trial participants are protected.

The post-holder will work with the research team to plan, implement, organise and manage concurrent research projects. S/he will develop networks with Multidisciplinary Teams across the Trust and other appropriate local and national agencies. S/he will coordinate and manage the relevant study portfolio and deliver recruitment accrual in line with performance and monitoring objectives.

Key Dimensions:

The post holder will be responsible for the implementation and monitoring of the clinical requirements associated with research to ensure optimum delivery of clinical trials. S/he will ensure that all research procedures are conducted according to study protocols and will be accountable for the recruitment, data collection and care of research participants with a focus on providing a quality experience.



Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

PRIMARY DUTIES & AREAS OF RESPONSIBILITY

Leadership

- 1. Have an understanding of the clinical research team work-plan and contribute to its achievement.
- 2. Manage research performance and study timelines of relevant studies.
- 3. Collaborate with other Trusts and organisations within the region to improve research delivery.
- 4. Keep up to date with research management issues through liaison with other Research Specialists /Team leaders and link with national networks.
- 5. Provide relevant supervision and mentorship to members of staff and students.
- 6. Take responsibility for own health, safety and security and promote the health, safety and security of the wider team.
- 7. Contribute to the development and implementation of clinical and research policies, procedures and SOPs.
- 8. Facilitate and maintain effective communication within the research team and between the multidisciplinary clinical team.
- 9. Assist in the delivery of education and training regarding research for the wider Multidisciplinary Team and act as an ambassador for research.
- 10. Promote a blame free culture in reporting incidents and where appropriate support local investigation of incidents.
- 11. Support appropriate studies within PHNT/UHP and its partner organisations as appropriate.

Research

- 1. Be responsible for the delivery of a clinical trial portfolio relevant to the specialty.
- 2. Ensure that the delivery of studies meet requirements with regards to the Department of Health's Research Governance Framework for Health & Social Care and the EU Clinical Trials Directive by implementing quality systems.
- 3. Participate in Good Clinical Practice (GCP) training.
- 4. Contribute to the Expression of Interest / Study Selection process for the relevant specialty.
- 5. Contribute to study set up, recruitment planning and study delivery.
- Lead forward and contribute to Patient and Public involvement activities.
- 7. Be responsible for promoting the appropriate referral and recruitment of patients to clinical research studies. Work with the clinical trials team and investigators to develop strategies to overcome barriers to recruitment and to solve other problems relating to specific studies.
- 8. Coordinate and run study visits including off site visits whilst adhering to the lone worker policy.
- 9. Work with other departments within the Trust to ensure that trial specific investigations and procedures are undertaken as required by the trial protocol, in order to establish eligibility and safety of patients within clinical trials.

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

- 10. Contribute to the accurate costing for clinical trials
- 11. Ensure clear, accurate and concise records are kept for research projects in accordance with all regulatory requirements including the Data Protection Act.
- 12. Ensure that data is transcribed accurately where required and assist with the maintenance of the Trial Master File.
- 13. Respond to data queries generated by the study coordinating team within a timely manner.
- 14. Ensure the recording & reporting of adverse and serious adverse events that occur whilst the participant is in the clinical trial to the trial co-coordinator/Principal Investigator (PI) and R&D office in line with the study protocol, local policies and regulatory requirements.
- 15. Assess and evaluate the progress of on-going clinical trials for which the post holder has responsibility, maintaining accurate records of the status of studies and providing regular updates to the department on the status of the studies. This will involve ensuring that any Data Management Systems are updated with key trial data and validated efficiently.
- 16. Escalate on-going study performance issues to the Senior Research Nurse or Team Lead.
- 17. Co-operate with external and internal audit, data monitoring and quality assurance by working with R&D, sponsors, study monitors and external bodies.
- 18. Assist in study close down and the preparation of results of research for presentation as posters, abstracts, papers or scientific presentations.

Clinical & Professional

- 1. Be responsible for the care of research participants within the relevant sphere of practice and use opportunities to provide health promotion and patient education.
- Use relevant clinical knowledge to screen and identify patients suitable for clinical research using inclusion and exclusion criteria and utilising NHS records, screening clinics, visiting wards and outpatients and using Trust IT systems and databases.
- Act as a resource and role model for all aspects of Research Clinical Practice in order to optimise patient care and clinical practice this may include carrying out physical assessments, conducting sample retrieval and processing, providing or coordinating interventions and treatments, clinical monitoring.
- 4. Undertake all mandatory training and take part in personal development reviews.
- 5. Ensure the environment is suitable for patient care and research processes, recognising the importance of privacy, dignity and diversity.
- 6. Demonstrate professional development and an in-depth knowledge of current clinical and research practice.
- 7. Provide on-going advice and information to patients and their carers/families with regard to their participation in clinical research in order to facilitate effective informed consent.
- 8. Where appropriate receive and document written informed consent from research subjects. Training and support for informed consent will be given.
- 9. Be responsible for the safe and accurate collection of research data through clinical procedures such as venepuncture, history taking, standard observations (height, weight, BP, RR, HR, SpO2 temperature) and other assessments such as

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

- ECG, physical examinations, disease specific outcome measures, questionnaires, rated scales, qualitative interviewing as required by the protocol.
- 10. Centrifuge, process track and ship samples in line with protocol requirements.
- 11. Ensure the safe administration of any treatments and drugs given within the context of a clinical trial.
- 12. Monitor treatment toxicity/side effects and initiate changes to treatment as required by the protocol. Escalate any concerns to the Principle Investigator or relevant physician.
- 13. Ensure accurate patient trial documentation, including the use of electronic data capture systems and ensure relevant information is recorded in patients' medical notes and case report form in a timely manner.
- 14. Refer to other specialists as required in order to provide optimal care of the participant.
- 15. Contribute to the monitoring of clinical standards within the research team.
- 16. Treat all persons encountered during the course of duties with respect and courtesy and maintain a standard of conduct which best represents the clinical trials team and the Trust.
- 17. Work within the relevant professional code of conduct (if applicable) demonstrating accountability for own actions and awareness of own limitations.
- 18. Provide cover for other research nurses/ practitioners as required.
- 19. Proactively seek feedback from participants and their families during their research involvement.
- 20. Contribute to Patient and Public Involvement and Engagement activities across the department

Resources

- 1. Have an awareness of the income stream relevant to Clinical Trials and work within, local and Trust wide financial and budgetary guidelines.
- 2. Assist in accurate costings for clinical research activity during study set up. Utilise planning tools such as the DRIVE toolkit.
- 3. Assist in identifying resource implications for individual studies.
- 4. Ensure research equipment is maintained in an effective working and good clinical order.

Other Responsibilities:

1. To take part in regular performance appraisal.

Key working relationships:

Lead Research Nurse / Practitioner
Research Nurse Specialist /Team Lead
Senior Research Nurse / Practitioner
Clinical research team
South West Peninsula Clinical Research Network
Research and development team
Principal Investigators

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

Trust multidisciplinary team
Study participants and their families
Clinical trials pharmacy team
Diagnostic services
Study sponsors and Clinical Research Associates
CRN team

All Job Holders are required to...

- 1. Work to the Trust values Put patients first, Take ownership, Respect others, Be positive, Listen, learn and improve.
- 2. Adhere to Trust policies and procedures, e.g. Health and Safety at Work, Equal Opportunities etc.
- 3. Maintain personal and professional development to meet the changing demands of the job, participate in appropriate training activities and encourage and support staff development and training.
- 4. Attend statutory, essential and mandatory training.
- 5. Respect the confidentiality of all matters relating to their employment and other members of staff. All members of staff are required to comply with the requirements of the Data Protection Act 1998.
- 6. Comply with the Corporate Governance structure in keeping with the principles and standards set out by the Trust.
- 7. Comply with the codes of professional conduct set out by the professional body of which registration is required for the post.
- 8. Ensure they are familiar with the Risk Management Framework, follow policies, procedures and safe systems of work, make known any hazards or risks that they identify and take all necessary actions to reduce risk.
- 9. Ensure the welfare and safety of children within their care. This includes staff who come into contact with children and families in the course of their work as well as those staff who have a specific role with children and families.
- 10. Ensure they attend Child Protection training at the appropriate level within the specified time frame.
- 11. Staff must comply with Safeguarding Policies and Procedures in order to promote safeguarding and prevent abuse to vulnerable people using Trust services.
- 12. Maintain the prevention and control of infection and fully comply with all current Trust Infection Control policies and procedures.

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

13. Take responsibility for any records that they create or use in the course of their duties, in line with the Public Records Act and be aware that any records created by an employee of the NHS are public records and may be subject to both legal and professional obligations.

All Managers are responsible for...

- Assessing risks and implementing the necessary actions to minimise these
 risks within their sphere of responsibility. They must also enable staff to attend
 the relevant statutory and essential training.
- Managing attendance in accordance with the Trusts Attendance Management Policy.

All Heads of Departments are responsible for...

 Ensuring all necessary risk assessments are carried out within their division, Service Line or department in liaison with relevant sources of specialist support and expertise within the Trust. They must also ensure that the risk management process is completed appropriately.

Note

This job description is neither definitive nor exhaustive and is not intended to be totally comprehensive. It may be reviewed in the light of changing circumstances following consultation with the post holder. This job description is to be read in conjunction with all current Plymouth Hospitals NHS Trust policies, procedures & guidelines.

GENERAL

The nature of clinical research is such that flexibility is required from the workforce. Periodically it may be necessary to move staff within the different specialties in order to meet the needs of the portfolio and maintain the required skill mix. To meet our patient's needs, this postholder will be required to work weekends and night shifts as required.

This is a description of the job as it is now. We periodically examine employees' job descriptions and update them to ensure that they reflect the job as it is then being performed, or to incorporate any changes being proposed. This procedure is conducted by the Manager in consultation with the jobholder. You will, therefore, be expected to participate fully in such discussions. We aim to reach agreement on reasonable changes, but if agreement is not possible, we reserve the right to insist on changes to your job description after consultation with you

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

PERSON SPECIFICATION

4.TTDIDIJTE 0		DE01D 4 D1 E
ATTRIBUTES	Essential	DESIRABLE
Knowledge & Experience	Pertinent clinical skills Computer literacy including ability to work with databases. Ability to organise and prioritise own workload and work to tight deadlines. Ability to make independent decisions Understand the significance of research and use of validated results to improve practice Demonstrable experience with dealing with confidential patient information Ability to communicate complex information to patients/carers/ members of MDT Broad and recent clinical demonstrable experience relevant to the post	Proven knowledge of the Research Governance Framework and Good Clinical Practice Guidelines. Proven knowledge of clinical trials & research methodologies. Proven record of meeting targets Demonstrable experience of clinical research within the NHS or commercial setting Understanding of data collection and data entry for clinical trials.
Qualifications	Registered Nurse or Healthcare Professional, (if not a registered practitioner then significant appropriate clinical practice essential)	Research Training (e.g. GCP, degree module, informed consent)
Aptitude & Abilities	Ability to work autonomously Ability to work cohesively as a member of a multidisciplinary team High level of interpersonal and communication skills Flexible and adaptable Attention to detail	
Disposition / Attitude / Motivation	Willingness to learn, instigate and develop efficient working systems Willingness to undertake any necessary training and development to enhance work performance Commitment to openness, honesty and integrity in undertaking the role Willingness and ability to work across sites including community	
Other Factors		

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015

Appendix 2 – Sign-off-sheet



AGENDA FOR CHANGE

Post Current Grade
Directorate/Speciality
Department
DECLARATION:
Post Holder:
I confirm my agreement that this Job Description & Job Specification are a proper reflection of my job and that I am happy for them to go forward to the Agenda for Change Job Matching Process.
Signed Date
Full Name
Line Manager:
I confirm my agreement that this Job Description & Job Specification are an accurate reflection of the job of the post-holder for whom I am responsible and that I am happy for them to go forward to the Agenda for Change Job Matching Process.
Signed Date

Agenda for Change	Version 10
Author: Claire Ackerman	Date: June 2015