

Lead Research Nurse Specialist for QA and Education

'Ensuring a Continual Cycle of Quality and Responsive Education'

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Background: In Clinical Research it is necessary to establish and maintain quality assurance systems to ensure compliance with regulations and concordats relevant to clinical research delivery. To supplement this paradigm we created a role, **Lead Research Nurse Specialist (LRNS)** to provide experienced and specialised clinical support for Nurses/AHPs setting up and delivering complex and ward-based IMP studies as well as supporting the ongoing education of the research delivery workforce by sharing learning through incident reporting as well as through programmes of study monitoring and audit.

It was recognised that the need for additional support, collaboration and integration of our research in line with our increasing portfolio of ward-based and complex studies was necessary, our ward nurses needed more support and practical guidance from us to ensure study drug administration and accountability were in accordance with the study protocol thereby ensuring participant safety as well as data integrity. The Lead Research Nurse Specialist role was created to provide strong links with the clinical areas as well as the sharing of learning and best practice with research delivery staff.



The Role in Practice – Quality and Learning

Clinical Support

The LRNS offers an opportunity to provide expertise and specialised 'hands on' support for the clinical areas involved with clinical research ensuring the efficient running of research projects inclusive of the nursing element, contributing to achieving the highest standard of patient care within the clinical area.

With this oversight the LRNS also monitors all incident reporting related to clinical research and participates in identifying themes and areas for action and escalation. The LRNS acts as a Clinical Nursing Lead for research, representing research within Trust governance groups and being a resource on Root Cause Analysis when required.



Education – meeting ongoing educational needs

The LRNS, as the Education Team Lead, plays a key part in developing the education strategy for the research delivery workforce alongside the senior leadership team. This includes overseeing delivery of the induction programme, as well as regular and relevant responsive sessions forming part of the research workforce ongoing education and development. These sessions are responsive in nature because they are formed from identifying areas of learning and development following a programme of internal study monitoring and audit as well as learning from incident reporting. This contributes to equity in standards across all research areas and early identification and resolution of issues leading to improved participant safety and high quality data collection.



IMPACT

Research and Clinical Integration:

Supporting ward-based & complex studies

Providing research expertise at study feasibility promoting effective study set up and plans for study IMP accountability, particularly for those studies where ward administration is part of the study protocol. Responding and coordinating incident reporting for ward-based IMP studies working with the clinical areas to resolve any issues together. Working with the trust as a member of the Medications Safety steering group.



A snapshot of studies receiving LRNS input

A specialist role providing an effective clinical link

The LRNS acts as a clinical nursing lead for research work within the trust. The LRNS sits on relevant steering groups ensuring research involvement in innovation and new processes. Integrating the digital agenda into nursing/midwifery processes is one example of research presence having a central part to play in these ongoing developments.

The LRNS is part of the clinical nurse specialist community which has been valuable for the integration of research into the clinical area as well as mitigating risk for research participants.

Education:

Programme of Internal Study Monitoring and Audits

Studies undergo either full internal monitoring or 'snap-shot' audits, for example; GCP and CV compliance or Informed Consent Forms correctly completed and stored.

The purpose of monitoring/audits is to confirm and address quality but predominately to share best practice and learn, improve and refine processes. Findings from this programme can swiftly be added to regular education updates and sessions ensuring prompt and responsive action.

Programme Of Responsive Education

- 'Research Education Spotlight' – shared monthly
- Feedback from monitoring/audit findings
 - Learning from incident reporting
 - Regular consolidation sessions



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