SOUTH TYNESEIDE AND SUNDERLAND NHS FOUNDATION TRUST

JOB DESCRIPTION

Job Title  Research Governance Facilitator

Division

Department/Ward  Research and Innovation

Location  South Tyneside District General

Main Purpose of the Job

The post-holder will be responsible for the implementation and delivery of systems to support the review, set up and on-going monitoring of research studies across the Trust. The post holder will also be required to support the Trusts sponsored research portfolio, assisting in the governance setup of external research sites.

The successful applicant will work in collaboration with the R&I Manager and research delivery teams to review the trusts capacity and capability to participate in research studies. Once a study has commenced they will be responsible for day to day monitoring of the study. Their role will involve working with research delivery teams and support departments to identify any issues with studies and assist with resolution along with the R&I Manager.

They will be responsible for the annual audit of a sample of research studies to ensure compliance with national and local regulations, frameworks and Standard Operating Procedures (SOPs). In addition they will work alongside colleagues from the National Institute for Health Research Clinical Research Network for North East and North Cumbria (NIHR CRN:NENC) to review the set–up and recruitment of commercial and non-commercial studies and provide information to the Department of Health on our “Performance in Initiation and Delivery” of research (PID)

The post holder will be primarily based at South Tyneside District Hospital with regular requirement to travel between hospital sites and attend regional meetings.
**Dimensions**

The post holder will co-ordinate the capacity and capability review of research within the Trust, expected to continually review and revise processes in line with the latest HRA guidance and may be required to contribute to regional working groups.

Monitor all studies to make sure they adhere to all applicable legislation (such as GDPR) and/or frameworks, and that studies are meeting required recruitment targets/High Level Objectives (HLOs).

Review study amendments to determine local implications and changes to resource requirements.

Perform an annual audit of a selection of studies in line with R&D SOPs to ensure compliance with relevant legislation, frameworks and Trust SOPs.

Review and report on the performance metrics relating to the setup, status and delivery of commercial NIHR portfolio studies.

Assist with the development and maintenance of information on the Local Portfolio Management System (LPMS) that is used to record all research related data locally in the Trust and regionally in the network. Attend and report back from any regional meetings relating to LPMS development. Also provide training to research delivery staff on the use of LPMS.

Provide instruction to researchers on the IRAS and HRA approval system, explaining the ethical and legal requirements for NHS research.

Attend conferences and workshops related to the post.

A high level of initiative is required in order to act autonomously and plan own workload.

**Organisational Chart**

The purpose of this section is to establish how the job fits into the rest of the organisation. Please highlight job and show colleagues on same level and two levels above and below.

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Head of Research

Research Management and Governance facilitator (this post)

Research admin
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**Communications and Relationships**

Required to build strong relationships with staff in other research departments, Chief Investigators, Principal Investigators and other research staff to identify their needs in meeting all the responsibilities imposed by UKCRN Operating Guidelines, Department of Health legislation and Government Frameworks.
A high level of negotiation and understanding of issues pertaining to research is required and the post holder is expected to liaise with commercial and non-commercial sponsors, as appropriate. There are a number of key differences with each project, which makes the communication complex and requires attention to intricate detail.

The post holder is likely to have regular contact with the following groups:

- R&D managers/leads/facilitators across the North East and other NHS providers
- Staff at all levels within the Trust. The post holder will ensure that the necessary documentation are uploaded to LPMS and available to other Trusts. This will involve liaison with Trust R&D staff and research teams across the country and in the devolved administrations
- Research Ethics Committees
- Academic institutions
- CRN NENC and the National Institute for Health Research (NIHR)

Post holder will be an active member of the Trust Research Management and Governance Group and make recommendations as appropriate.

**Knowledge, Skills, Training and Experience**

Knowledge of new legislation, requirements and developments relating to research in the NHS, research governance, CRN developments and regulatory requirements in order to carry out their role

A high level of initiative is required in order to act autonomously and plan own workload to meet timelines for NIHR HLOs.

Initiative to progress applications within the policy frameworks, making decisions and judgements that are commensurate with the scale of the research, based upon an assessment of risk, assessing where managerial input is required

Analysis, interpretation and comparison of large amounts of complex research information provided both from local and national sources, providing summaries and highlighting trends/issues as required

Demonstrable IT skills

Experience in managing complex information

Proven experience of working to deadlines

Proven experience of dealing with a busy workload

Ability to delegate where appropriate

Excellent attention to detail

To work in accordance with ICH Good Clinical Practice and research governance standard

**Key Result Areas**
**Patient/Client Care**

Review patient facing research information such as patient information leaflets and consent forms

Liaison with patient research ambassadors

Ad-hoc contact with patients at events/conferences

**Human Resources**

Act as a resource for colleagues and external stakeholders providing advice and support on the set up of NHS research

Regular liaison with HR to ensure researchers have research passports and letters of access to undertake research across the Trust.

Assist with the induction and education of new staff members

Attend team meetings and contribute to the development of the team

Proactively contribute to your own personal and professional development including setting objectives during New Staff and Staff Development Reviews.

**Information Resources**

Produce updates and reports pertaining to all research activity – the post holder will be required to use a wide range of computer systems including LPMS and NIHR ODP

Produce updates for research meetings/reports relating to the progress of studies awaiting HRA approval and/or local confirmation.

Assist in the development/maintenance of the Trust research website, research newsletters etc

**Policy and Service Development**

Assist in the development of standard operating procedures and work instructions.

Identify barriers to performance and continually consider and implement service/process improvements

**Research and Development**

Be aware of developments in research governance, ethics and other regulatory and legal guidelines governing clinical research.

Co-ordinate the capacity and capability review of research within the Trust

Monitor all studies to make sure they follow all applicable legislation and/or frameworks, and that studies are meeting required recruitment targets.

Review study amendments to determine local implications and changes to resource requirements

Proactively promote research and the local study portfolio
### Freedom to Act
This section should specify the level of autonomy and supervision required in this post.

- Work under the direction of the R&I manager
- High level of initiative required to manage own workload
- Answer day-to-day queries as guided by internal policies and procedures: advise researchers and research support staff on the approvals process for research projects, including the interaction with CRN, Ethics Committees, etc
Effort and Environment

Physical
Please describe circumstances, frequency and the degree of effort required.

- Prolonged periods at a computer
- Occasional lifting and handling

Mental
Please describe the scope, circumstances and frequency of exposure.

- Meeting strict deadlines
- Periods of prolonged concentration
- Manage a varied and often unpredictable workload, responding to conflicting demands and pressures

Emotional
Please describe the exposure and involvement in distressing situations.

- Provide effective emotional support team for staff

Working Conditions
Please describe the type and extent of exposure to unpleasant working conditions/hazards.

Signed: ________________ (Job Holder)  Date: ________________

Signed: ________________ (Line Manager)  Date: ________________
## Person Specification Guidance

**Job Title:** The job title should exactly match the job title on the Job Description.

It is crucial that the Essential Criteria listed in the Person Specification under Qualifications, Experience, Skills, Attributes and Knowledge summarise the responsibilities described in the body of the Job Description, and are not stand alone requirements of the post-holder.

<table>
<thead>
<tr>
<th>Criteria relevant to the job</th>
<th>Essential Criteria</th>
<th>Desirable Criteria</th>
<th>Method of assessment</th>
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<tbody>
<tr>
<td><strong>Qualifications</strong></td>
<td>Diploma level or equivalent relevant experience</td>
<td>ICH Good Clinical Practice (GCP)</td>
<td>Application/Interview</td>
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<td>Working experience of a research department</td>
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<td>An awareness of the National Research agenda and NIHR initiatives</td>
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<td>Attendance at all relevant CRN Training Courses</td>
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<td><strong>Experience</strong></td>
<td>Experience of effectively managing research systems/databases and co-ordinating research applications</td>
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<td>Significant research experience</td>
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<td>Broad knowledge, skills and experience in Research Governance</td>
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<td>Experience of research Audit and Monitoring</td>
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<td>Skills and Knowledge</td>
<td>Extensive knowledge of research in the NHS, research governance and research systems such as LPMS and NIHR ODP</td>
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<td>Advanced keyboard skills – ECDL or equivalent experience</td>
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<td>Excellent written and oral communication skills, including presentations – Ability to communicate with staff at all levels</td>
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<td>Excellent communication skills with outside agencies, other research active Trusts and region wide active researchers.</td>
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<td>Ability to manage conflicting priorities - proven time management skills, working accurately with meticulous attention to detail.</td>
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<td>Flexibility including the ability to work effectively individually and within a team and relate well to others.</td>
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<td>Excel skills – interrogating data</td>
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<td>Physical skills</td>
<td>Car driver, willing to work and travel across all hospital sites</td>
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<td>Knowledge of ICH Good Clinical Practice regulations</td>
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<td>Experience building relationships with stakeholders and partners</td>
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<td>Previous experience working in a multidisciplinary team within a healthcare or research environment</td>
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<td>Office management and clerical skills</td>
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