#### **JOB DESCRIPTION**

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| 1. JOB IDENTIFICATION |
| Job Title: Research and Development (R&D) Research Coordinator  (Band 6)Responsible to (insert job title): Assistant Director Research, Innovation and Knowledge (RIK)Department(s): Research, Innovation & KnowledgeDirectorate: Medical Directors’ (NHS Fife) DirectorateOperating Division: CorporateJob Reference:No of Job Holders: 2Last Update (insert date): Aug 2023 |

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| 2. JOB PURPOSE |
| The R&D Research Coordinator will be a core member of the Research, Innovation & Knowledge (RIK) Team with a specific remit of supporting activity by working with the Assistant Director RIK, Commercial Manager, Quality & Performance team and Lead R&D Research Nurse.Specifically to facilitate approval of research projects and amendments in a timely way. Responsible for supporting researchers/staff with enquiries and applications for Research EthicsCommittee (REC) and R&D approvals and amendments via the Integrated Research Application System (IRAS). To provide an efficient and effective administrative and facilitative support service to the RIK team to meet national priorities and targets. To implement thorough management approval processes prior to the initiation of NHS basedresearch activity and within strict timelines. Dealing with enquiries, advising and supporting applications for approval from individual researchers (NHS and academic) and pharmaceutical companies and multi-site studies, via NHS Research Scotland Permissions Co-ordinating Centre (NRSPCC).To contribute to the development of a resourceful and flexible RIK team which interfaces successfully with the Chief Scientist Office (CSO), external funders and sponsors, and partner NHS organisations.Responsible for the line management of the R&D Support Officer and the R&D Approvals Assistant. |

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| **3. DIMENSIONS** |
| NHS Fife is responsible for the health of a population of over 370,000 people across Fife. Services are delivered through Acute based services located at Queen Margaret Hospital, Dunfermline and Victoria Hospital, Kirkcaldy. Our Health and Social Care Partnership provides primary and community care, mental health, learning disability and children’s services.The RIK Department provides a service to all research active, and any potentially research active health care professionals from within NHS Fife. The post holder will work as part of the RIK Support Team and will have responsibility for progressing Research, Innovation & Knowledge activity within a large complex organisation. Reports directly to Assistant Director RIK and obtains assistance from Assistant Director RIK. |

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| **4. ORGANISATIONAL POSITION** |
| See Appendix 1 |

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| 5. ROLE OF DEPARTMENT |
| The RIK department is responsible for the management of high quality Research, Innovation and Development in NHS Fife in line with strategic direction and statutory legislation.The department is responsible for the effective management of Chief Scientist Office funds, commercial research revenue and grants.The department is also responsible for developing the infrastructure and culture in which research in NHS Fife will continue to grow and contribute to evidence-based practice.The department is incorporated into the Corporate Directorate, in order to provide assurance that systems and processes are working in line with the UK Policy Framework for Health and Social Care Research, working in partnership with local universities and Scottish Research Networks to increase Scottish patient access to clinical research.Clinical Research Facilities (CRFs at QMH and VHK) provide dedicated facilities to further increase research activity and opportunities to progress commercial / non commercial clinical research and collaborative ventures within NHS Fife. |

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| 6. KEY RESULT AREAS |
| **MANAGEMENT APPROVAL AND AMENDMENTS*** Responsible for ensuring that the research project negotiation and approval process is speedily and accurately taken forward in line with the Chief Scientist Office (CSO) required timelines, Coordinating the approvals process, collating documents, cross checking, identifying any issues and ensuring appropriate funding, sponsorship, indemnity provision, risk assessment, regulatory approvals and any other approvals are in place prior to recommending studies for approval.
* Provide key point of contact within the Research Office for external funders and sponsors, partner NHS organisations, to provide advice and support around approvals, ethics, amendments, costing, completion of IRAS (Integrated Research Application System) application forms, other general enquiries. Ensuring high standard of response to enquiries, and providing a comprehensive administrative service to the RIK team as required.
* Providing advice and assistance around categorisation of projects (research/audit/service evaluation) and routes for approvals.
* Deals with requests for sponsorship by NHS Fife, checking indemnity arrangements, coordinating risk assessment review, liaising with Medical Director to submit Sponsorship request and paperwork and supports researcher with documentation and submission of IRAS application.
* Works with colleagues in Pathology and Finance to help coordinate tissue requests relating to research studies in cases where the research may not be taking place in Fife. Reviews paperwork, ensures relevant approvals are in place and arranges to an authorisation letter to be prepared and signed on behalf of the Medical Director authorising the release of tissue and ensuring that colleagues in Finance are aware of any reimbursement so that these can be invoiced and funds directed to Pathology in due course.
* Works with colleagues in Information Governance to ensure that data protection aspects of proposed studies are robust and any other approvals such as Caldicott Guardian or Public Benefit and Privacy Panel (PBPP) are in place where required.
* Liaising with researchers where necessary to obtain information on, progress of study, amendments and any other changes to the study.
* Ensure compliance with and awareness of appropriate research Directives and Legislation and their implications for research.
* Review protocol amendments, negotiating any additional financial charges incurred (where appropriate) as a consequence of any amendments and assisting with revising contractual documentation as necessary. Coordinating these changes with relevant departments and researchers.
* To advise researchers about the need for Honorary Contracts and Letters of Access according to current national guidelines and advice from Human Resources where necessary to initiate, review and process Research Passports and NHS to NHS pro-formas. Prepare and issue Letters of Access/Research Passports as required on behalf of HR.
* Participate and assist in the preparation of feasibility assessments, site selection and Regulatory visits where required.

**MANAGEMENT SYSTEMS*** Responsible for developing, maintaining and maximising effectiveness of an up to date and complete register of all commercial and non-commercial research projects within NHS Fife, using electronic systems such as the EDGE Clinical Research Management System and SReDA (Scottish Research Database Application) in regard to the creation, modification tracking and upkeep of study project records.
* To help develop clear Standard Operating Procedures (SOPs), Working Instructions and other documentation to facilitate management and administration of research within the NHS.

**OTHER*** Takes part in regular and ad hoc meetings with the wider team. Part of the RIK Leadership Team.
* Participate in the provision of multidisciplinary training/educational activities where required to enable staff to carry out research activities. Also providing ad hoc advice and training as and when required.
* Establish close working relationships with other RIK Staff within Fife, including the R&D Research Nurses, the Research Ethics Service, Finance Office staff, Pharmacy Staff, Pathology staff, Information Governance staff, HR and other relevant research partners within Fife and represent NHS Fife at relevant local and national meetings as required.
* In the absence of the Assistant RIK Director, deputise in approval-related matters where appropriate.

**LINE MANAGEMENT*** To line manage and develop the R&D Support Officer post. Have delegated responsibility for the day-to-day leadership and supervision of the Support Officer and, with the Assistant RIK Director, will be involved in staff recruitment, management, personal development planning, absence management, facilitating returns to work, appraisals and responsible for disciplinary/grievance matters for staff who are line managed.
* To line manage and develop the R&D Approvals Assistant. Have delegated responsibility for the day-to-day leadership and supervision of the R&D Approvals Assistant. This involves regular communication to ensure flow of work, prioritisation, understanding of requirements, reviewing and checking work where necessary. With the Assistant RIK Director, be involved in management, personal development planning, absence management, facilitating returns to work, appraisals and responsible for disciplinary/grievance matters.
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| 7a. EQUIPMENT AND MACHINERY |
| * Use of a computer is vital for database management, analysis and development of reports. It is also vital to communicate both accurately, quickly and efficiently with colleagues, internal and external researchers and national bodies for Research, Innovation and Development projects.
* Use of a telephone (including voicemail and call transfer systems), photocopier, printers, scanners, binder, shredder and Projector are also essential in carrying out duties.
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| **7b. SYSTEMS**  |
| The post holder is responsible for the development and application of the following systems within their role:* The post holder adheres to departmental and organisational Policies, SOPs and Work Instructions.
* Electronic data storage system - to store data to the appropriate location within personal drive, shared drive or remote drive.
* Electronic diaries systems (EDGE and OUTLOOK) - to ensure these are shared across the team.
* SReDA and EDGE databases - updating these with accurate data regarding Research studies and producing reports for various groups and committees.
* Q-Pulse database – reviewing and acknowledging R&D Policies, SOPs and Work Instructions as and when required.
* Communicating by e-mail with colleagues, researchers and other support services.
* Using Teams/telephone to communicate with colleagues, researchers and other support services.
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| 8. ASSIGNMENT AND REVIEW OF WORK |
| * The post holder is responsible to the Assistant RIK Director. The majority of the post holder’s work is generated via e-mail and other electronic systems. Work may be delegated directly from the Assistant RIK Director or any other team members. The post holder is therefore responsible for managing and prioritising this workload to deal with relevant deadlines and timelines.
* The post holder’s work is determined and evaluated through annually through the TURAS appraisal system and reviewed on a regular basis.
* The post holder uses own initiative to deal with day-to-day problems and routine enquiries.
* The post holder is guided by precedent and clearly defined policies, protocol/procedures or codes of conduct.
* The post holder will attend regular meetings to feedback, review and discuss all work in progress.
* The post holder is Line Manager for and can allocate work as required to the R&D Support Officer and Approvals Assistant.
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| **9. DECISIONS AND JUDGEMENTS** |
| * The post holder is responsible for planning the order of work based on the current workload and is expected to use initiative, logic and discretion when making judgments about work prioritisation and identifying solutions to problems.
* The post holder will prioritise workload on a daily basis adapting as circumstances change and new priorities emerge, dependent on demand, workload and time available.
* The post is autonomous, but support can be sought and given from the Assistant RIK Director or other member of the wider research team with appropriate expertise or experience.
* A high level of discretion, sensitivity and maturity is expected when dealing with confidential information as to how information should be handled, recorded and reported.
* Typical judgements which might be made are:
* Assisting with the determination of study categorisation (e.g. research/audit/service evaluation) and advising appropriate route for processing
* With advice where required from colleagues, assisting with data protection and information governance issues. Determining the need and assisting with preparation and sign off of Caldicott Guardian approvals and PBPP
* Liaising with researchers to provide advice and guidance on the IRAS application system, NHS Research Ethics, HRA templates and other national guidance
* Providing advice and information around the requirement and use of Research Passports, Honorary Contracts, Letters of Access
* Liaising with Sponsors and external Study Coordinators to provide updates on progress of approvals and amendments
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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB* Dealing with conflicting demands whilst working to tight schedules and ensuring that accuracy and quality standards are maintained, with minimal supervision.
* Thorough understanding of guidelines and regulations relating to Clinical Research.
* Good time management skills are required to enable the management and prioritisation of a varied and highly demanding workload whilst adhering to tight deadlines.
* Dealing with difficult situations involving researchers that require tact and diplomacy
* Concentration is required when reviewing project information, data, checking and reconciling information, answering queries, producing reports, attending meetings etc.
* The post holder will frequently be required to switch tasks and re-prioritise workload.
* Responding as promptly as possible to enquiries and queries.
* Updating and maintaining accurate records within various electronic systems
* Maintaining effective communication with a variety of individuals and organisations.
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| **11. COMMUNICATIONS AND RELATIONSHIPS**  |
| Regular face to face, e-mail and Teams/telephone contact with:InternalRIK Team - Day-to-day issues pertaining to study progress, approvals, amendments, feasibilities etcAll grades and disciplines of staff – Provide assistance, support and advice on approvals and amendmentsLiaise with and support hospital departments such as pharmacy, radiology, labs, and any other relevant departments as required for review of approvals and amendments.Actively participate in RIK Department and Monthly R&D Nurse Meetings.ExternalR&D Offices in other Health BoardsChief Investigators and Sponsor representatives from non-commercial organisations.CRAs and Sponsor representatives from pharmaceutical companies. |

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| **12. PHYSICAL, EMOTIONAL, MENTAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| Physical:Advanced keyboard skills required; prolonged periods using mouse and VDURequirement for sitting for extended periods of time on most days. * Requirement to work flexibly – mainly hybrid working, but to be available to attend on site if and when required and safe to do so.
* Requirement to attend online and face to face meetings across Fife and elsewhere

**Emotional:**Dealing with difficult situations involving researchers that require the exercise of tact and diplomacy Supporting staff to undertake projectsManaging and supporting the R&D Support Officer and Approvals Assistant**Mental:*** High level of prolonged concentration is required whilst reviewing study documentation, entering project information/data, producing reports
* Need to balance conflicting demands and priorities
* Pressure to meet deadlines
* High degree of flexibility required

**Environment Demands:*** Requirement to use VDU equipment more or less continuously on most days.
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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB  |
| **ESSENTIAL*** Educated to HND level or equivalent relevant experience.
* Excellent interpersonal skills and the ability to work as part of an interdisciplinary team.
* Excellent verbal and written communication skills.
* Good time management and multitasking skills, able to prioritise workload and work to tight deadlines.
* Strong project planning and organisational skills with excellent attention to detail.
* Highly computer literate, with a working knowledge and experience of all Microsoft software packages.
* Knowledge of Database packages including experience pulling reports, manipulating and presenting data.
* Thorough understanding of the Regulations and Guidelines relating to the conduct of Clinical Research, Information Governance, and the Data Protection Act(s).
* Flexibility to provide updates on data to a range of stakeholders.
* Ability to use own initiative and work independently, without direct supervision.

**DESIRABLE*** Experience working within an NHS environment.
* An awareness of the Health Service in Scotland in particular the Research & Development structures including national priorities relating to research governance.
* Ability to negotiate with a range of staff to ensure data is recorded appropriately and to ensure that problems relating to research data are resolved quickly, effectively.
* Knowledge of medical terminology is helpful when reviewing study documentation.
* “Mandatory Induction Standards and Code of Conduct for Healthcare Support Workers – NHS Circular CEL(2010)23
* Your performance must comply with the “Mandatory Inductions Standards for Health Care Support Workers in Scotland” 2009; and with the Code of Conduct for Health Care Support Workers, both as amended from time to time, which will be issued with your contract (further copies can be obtained from Human Resources). Failure to adhere to the Standards or to comply with the code may result in poor performance measures or disciplinary action and could lead to dismissal; or if you are self-employed, such failure will be deemed to be a breach of an essential term of your contract, allowing us to terminate with or without notice."
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| **14. JOB DESCRIPTION AGREEMENT** |
| A separate job description will need to be signed off by each jobholder to whom the job description applies.Job Holder’s Signature:Head of Department Signature: | Date:Date: |

**Appendix 1 Organisation**

**NHS FIFE RESEARCH, INNOVATION & KNOWLEDGE (RIK) SUPPORT STRUCTURE**

RN

Research Nurse

Line Management

Support & Advice

Professional Accountability

Legal Services

Medical Director Executive Lead for RIK

Assistant RIK Director

Assistant Director of Finance

R&D Lead Research Nurse

R&D Quality & Performance Lead

R&D Coordinator

(this post)

Innovation

Manager

**R&D Clinical Research Assistant**

R&D Clinical Research Assistant

**R&D Clinical Research Assistant**

Generic

R&D RN

Band 5

CSO Generic

R&D Snr

RN Band 6

Project-specific

Snr RNs

Band 6

WTE1.5

Generic /Haematology Snr RN Band 6

R&D Clinical Trials Pharmacy Technician

Associate Director of Nursing

Lead Pharmacist

Generic /Oncology Snr RN Band 6

Generic / Diabetes R&D Snr

RN Band 6

Stroke / Generic R&D Snr RN Band 6

Generic

R&D

Snr RN

Band 6

Generic

R&D

Snr RN

Band 6

Generic

R&D RN

Band 5

Generic

R&D RN

Band 5



R&D Support Officer & Approvals Assistant

Innovation Admin Officer

R&D Quality & Performance Assistants

LKS Assistant

Librarians (x2)

Library and Knowledge Services Manager

R&D Business Accountant