#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
|  Job Title: Associate Director of Research, Innovation and KnowledgeResponsible to: Medical DirectorDepartment(s): Research, Innovation and KnowledgeDirectorate: Medical Director’s DirectorateOperating Division: Corporate Job Reference:No of Job Holders: OneLast Update: May 2022 |

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| 2. JOB PURPOSE |
| The Associate Director for Research, Innovation and Knowledge is a senior leadership portfolio-based role with corporate responsibility for working across NHS Fife. On behalf of the Medical Director the Associate Director for Research, Innovation and Knowledge is responsible for the strategic and operational delivery of the Board’s agenda across the following domains:* Research and Development
* Innovation
* Knowledge and Library Services

The postholder has responsibility for ensuring Research Governance management and regulatory compliance across the whole of NHS Fife, as set out in the UK Policy Framework for Health and Social Care Research, Medicines for Human Use (Clinical Trials) Regulations 2004 and guidelines of ICH Good Clinical Practice. It is focussed on increasing research capacity, pharmacovigilance / other quality and compliance issues relating to clinical research and research capability. The postholder is responsible for ensuring Innovation Governance management and regulatory compliance across the whole of NHS Fife, consistent with guidelines from the Chief Scientists Office, Scottish Government and the Medicines and Healthcare Products Regulatory Agency (MHRA).The post holder will:work autonomously across the organisation and regionally leading on a portfolio of work based on the priorities of the Board, the priorities of NHS Research Scotland (NRS) and the Chief Scientists Office (CSO), working with Directors, Associate Directors, and other leadssupport the delivery of high-quality clinical research, innovation, and knowledge servicescoordinate and connect a large range of work within their portfolio requiring the post holder to manage change effectively to deliver successful outcomes across the organisation and for the regionprovide leadership on ad-hoc projects to enable the delivery of objectives aligned to the Medical Director or other Directors as appropriate; andwork at the interface between NHS Fife, other NHS Boards, the East Node (NHS Tayside, Fife and Forth Valley) Southeast Scotland Innovation Hub (HISES), Chief Scientists Office, Scottish Government, higher education providers, in particular the University of St Andrews, and other partnership agencies on a local, Regional and National level.The post holder will be required to deputise for the Medical Director in relation to areas of responsibility.The post holder will be required to lead and assist in other duties which are deemed reasonable to their role and band. |

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| **3. DIMENSIONS** |
| The post holder will provide strategic leadership for the following services in relation to the portfolio of work across NHS Fife and in the Southeast region. * Research and Development
* Innovation
* Library and Knowledge Services

The post holder is responsible for 39.6 WTE and an operating budget of approx. £2,000,000The post holder will have a delegated budgetary approval of £50,000.The postholder will have responsibility for recruitment, agreeing objectives, supervising work, agreeing personal development plans, and authorising travel expenses, annual leave and study leave.This is a Fife wide post. NHS Fife provides patient services from the Victoria Hospital, Whyteman’s Brae, Queen Margaret Hospital, Stratheden Psychiatric, Adamson Community Hospital, St Andrews Community Hospital, Glenrothes Hospital, Cameron Community Hospital and Randolph Wemyss Community Hospital. The population of Fife is approximately 370,000.The post holder will be responsible for progressing the domains detailed in Section 2 above. The remit covers all relevant activity within the Acute Services Division, the Health and Social Care Partnership and Corporate Services. In addition, the post holder will be responsible for managing the interface with partner organisations such as Southeast Health Innovation Hub (HISES), Chief Scientist Office Innovation team, Innoscot Health, NES, NSS, Scottish Government, the University of St Andrews and other higher education providers. The Research, Innovation and Knowledge (RIK) portfolio operates as a connected team, across Queen Margaret Hospital, Dunfermline (R&D, I & LKS), Victoria Hospital Kirkcaldy (Clinical Research Facility and LKS), Stratheden (LKS) and handling all NHS Fife research and innovation matters. It has responsibility for non-commercial, commercial, innovation and Intellectual Property (IP) activities, providing an expert advice service to all levels of staff and partners undertaking / wishing to undertake RD&I activities within NHS Fife. RIK has expanded to deliver increased opportunities to patients / staff / researchers, comprising a team of 47 (39.6 WTE). |

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| 4. ORGANISATIONAL POSITION |
| Please see Appendix 1 (Research, Innovation and Knowledge Organisational Chart) |
| 5. ROLE OF DEPARTMENT |
| The Medical Director is the professional lead for medical staff and senior medical advisor to the Board and has executive responsibility for ensuring the organisation delivers high quality, safe and effective care for the population of Fife. The Medical Director is the Executive Lead for Research, Innovation and Knowledge (RIK). The Research and Development, Innovation and Knowledge and Library Service teams within RIK comprise of the following services and teams:* Research Approvals and Research Governance
* Research Quality and Performance Management
* Clinical Research Delivery and Support
* Research and Innovation Training and Education
* Innovation Approvals, Governance, Project Support, Intellectual Property
* Library and Knowledge Services

This post has a Fife wide remit and a regional contribution with the Southeast Region Health Innovation Hub and the East Node (HISES). |

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| 6. KEY RESULT AREAS |
| **Strategic and Operational** 1. Provide strategic leadership in the development of the RIK agenda for NHS Fife. This includes the development of associated performance management and monitoring systems and processes in order to provide assurance to the Board of the quality of RIK services. Examples include development of the Innovation Governance Framework.
2. Provide senior management advice and support to Executive Leads and other directors and senior managers where required to ensure that NHS Fife meets its research and development, innovation and library and knowledge service objectives.
3. Lead in developing and implementing the RIK Strategy, Innovation Governance Framework, Partnership and Stakeholder relationships and any other R&D or Innovation developments on behalf of the Medical Director.
4. Provide senior management direction and support to research, development and innovation strategy, governance, and oversight activity for NHS Fife on behalf of the Medical Director.
5. Provide senior business management leadership to the Library and Knowledge Service team
6. On behalf of the Medial Director and Chief Executive lead the development of the research, innovation, and knowledge component of a strategy to deliver the Board Ambition to achieve and support Teaching Hospital status.
7. Responsible for the oversight, response and reporting of breaches of clinical research misconduct and fraud to Sponsors, Medicines and Healthcare Products Regulatory Agency (MHRA) and the relevant professional bodies.
8. Translate Research and Innovation strategy into policy and action plans which will positively impact NHS Fife and the Southeast region.
9. Promote and support a culture of change, creative and leading-edge practice in research, research and innovation leadership and research management development across NHS Fife.
10. Ensure effective financial governance arrangements are in place for the Medical Directorate working with Finance Business Partners to ensure the department operates within its agreed allocated budget and Standing Financial Instructions. Demonstrate the effective and efficient use of all resources to meet both department and corporate financial objectives.

Leadership 1. Role model and promote NHS Fife’s organisational values
2. Take a leadership role in maximising the participation of staff in the development and implementation of the embedding of robust research and innovation governance systems.
3. Lead and provide direction for the co-ordinating of work and development of policy and procedures to establish governance systems to meet the requirements of the national framework for research management. Oversee the data collection and reporting to NRS and MHRA national notification system and represent NHS Fife at national groups.
4. Lead in the scoping, development, and implementation of the Joint Research Office with the University of St Andrews, supporting the Board ambition to achieve and implement Teaching/University Hospital status.
5. Provide leadership and direction in the preparation of the annual report and submissions to CSO.
6. Build clinical research and innovation capacity and capability within NHS Fife.
7. In partnership with senior colleagues, ensure that systems and processes are in place to ensure a proactive and effective organisational learning culture is visible and that NHS Fife values are demonstrated in all management and collegial relationships.
8. Maintain a contemporary knowledge of national research and innovation strategy, guidelines and best practice and develop and participate in national and local research and innovation networks and groups.
9. Act as key point of contact for implementing any actions which arise from MHRA inspections or recommended changes relevant to the portfolio.
10. Produce high quality written reports, occasionally at short notice to inform Executives, Committee members and others or new developments or emerging issues.
11. Lead the development and implementation of the NHS Fife RIK Strategy
12. Lead the RIK team to deliver required key quality and performance indicators to deliver high quality clinical research, innovation and library and knowledge services.
13. To act on a national level as the lead representative of NHS Fife for research and innovation business with all external agencies, and the following in particular: CSO; NHS Scotland Research Permissions Coordinating Centre (NRSPCC); HISES, SHIP, Scottish Health Innovations Ltd (SHIL), and the Universities of Edinburgh, Dundee, and St Andrews.
14. To lead on developing national partnerships, collaborations streamlining research and innovation governance and facilitating multi-site collaborations and working.
15. To lead in working extensively with industry to deliver commercial contract research and deliver long-term partnerships and platforms for commercial trials.
16. To lead on developing research capacity within NHS Fife, increasing multidisciplinary involvement and the involvement of nursing and Allied Health Professionals To lead the involvement of consumers in clinical trial work in line with NHS Fife’s PPIE Framework.
17. To lead on providing researcher support, ensuring that Research and Innovation Education training and education needs of research staff are identified and appropriate programmes are developed or identified to meet these needs.
18. To lead on effective communication, promotion, and dissemination of research activities. Ensure the development and maintenance of a RIK website, RIK articles/newsletter, and circulation of research, innovation and publications information to staff and users.
19. To represent NHS Fife at a high level in a wide variety of contexts with a range of external agencies, including the CSO, other NHS and government bodies and universities, providing the first point of contact for global Pharmaceutical, Contract Research Organisations, Life Science and Device companies. To provide and receive highly complex, highly confidential, and sometimes sensitive information, to a wide range of audiences, including NHS Boards and senior colleagues.

**People and Finance** 1. Directly responsible for the line management of staff within the RIK department including recruitment, development, performance, and employee relations.
2. Responsible workforce planning within the RIK Department and ensuring the development of specialist skills to deliver objectives.
3. Ensure that there are training programmes in place so that NHS Fife staff have the necessary skills and knowledge to comply with the risk management policy, incident reporting procedures, Duty of Candour requirements, adverse investigations and that risks are appropriately escalated through the governance structures.

**Legislation**1. To seek out and identify all relevant EU and UK legislation and guidance relevant to research and development and innovation, translating and implementing it locally.
2. To work within and maintain an up-to-date knowledge of publications relevant to Research and Tissue Governance, including the Declaration of Helsinki, Good Clinical (Research) Practice as per the ICH/MRC Guidelines and EU directive, National Research Ethics Service SOPs, Medicines for Human Use (Clinical Trials) Regulations, Human Tissue Act, Medical Devices Regulations, Mental Capacity Act, Health and Safety Act, Data Protection Act and associated NHS legislation and the Research Governance Framework for Health and Community Care.
3. To work within and maintain an up-to-date knowledge of the guidance and requirements of other authorities with links to Research and Innovation Governance, such as the MHRA, Human Fertilisation and Embryology Authority, the Administration of Radioactive Substances Advisory Committee and National Information Governance Board.
4. To advise the organisation with respect to indemnity, risks and specific legal duties when considering undertaking Sponsorship responsibilities for research activity.
5. To work closely with Legal Services and the Central Legal Office to verify sound contractual and indemnity arrangements of research and/or innovation contracts with NHS Fife.
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| 7. EQUIPMENT AND SYSTEMS |
| The post holder will require daily basis use of IT and office equipment (including mobile devices) for word processing, data analysis, reporting and preparing presentations examples of which include:Personal Computer/ laptop and relevant software applicationsFollow you PrinterPhotocopierAudio-visual equipmentTelephone There is a regular requirement to use software packages and systems to prepare reports, analyse data (e.g., research activity data or financial data) and prepare presentations. The post-holder will therefore need to be a competent user of the following:* Microsoft Office package including Word, Excel, PowerPoint, and Office 365
* Microsoft Teams
* Electronic and hard copy filing systems
* Datix- update maintain, populate, analysis and reporting
* TURAS, PECOS and SSTS
* SReDA database

Ensure secure filing, updating, and archiving (for up to 20 years) of extensive research project documentation as required by Regulatory Authorities. |

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| 8. ASSIGNMENT AND REVIEW OF WORK |
| The post holder will have a high degree of autonomy in determining the work priorities and methods. The post holder is accountable to the Medical Director for the delivery of agreed national and local targets and outcomes. The post holder is fully accountable for leading and driving progress within the established area of responsibility. The post holder agrees plans with the Medical Director and relevant NHS Fife Executive Leads and works closely with them to deliver objectives.As a senior member of the Directorate the post holder would expect to have close working relationships with NHS Fife Executive Directors Group, Fife Health Board, and the Chief Executive all of whom would have a significant input to the assignment of work.The post holder works autonomously within this framework and is expected to provide expert advice and leadership within and out with NHS Fife. Review of performance in the post is undertaken by regular reviews of objectives and appraisal by the Medical Director. Regular one-to-one meetings with the Line Manager will take place to ensure effective communication. |

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| **9. DECISIONS AND JUDGEMENTS** |
| Whilst the post-holder will be guided by existing Board policy and objectives, the work will largely be about the development of strategy which will influence, interpret, and change these policies and ways of working.Working on behalf of the Medical Director and Board, the post-holder will consider and interpret national guidelines and legislation relating to the area of work.The post-holder will make judgements about situations which are unique in nature and where there are numbers of highly complex aspects to be considered and develop acceptable solutions.In the frequent use of options appraisal methodology, judgements will involve highly complex facts which will require skilled analysis and a weighing up of the various options.The post-holder will require the ability to exercise a significant degree of initiative to lead the development and management of research and innovation programmes and initiatives.The post holder will exercise discretion, tact and judgement and display professional behaviour in all dealings with internal and external colleagues and members of the public.The post holder will comply with and implement all NHS Fife Policies and Procedures. |

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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| Providing leadership to develop a vision through effective engagement across a broad spectrum of agendasUnderstanding the corporate objectives of NHS Fife with an ability to develop systems that adequately identify performance to meet the objectives relative to research and developmentAdapting to a constantly and rapidly changing environment at local and national levels influenced by changing national priorities and regulations – operationalising these into actions for NHS Fife in often demanding timescalesIdentifying potential barriers and developing effective working relationships with clinicians and managers in NHS Fife to successfully implement the research and development and innovation strategy and associated policies, procedures, and practices. Developing and managing research within a challenging multifaceted environment, whilst balancing the needs and demands from a wide range of internal and external stakeholders. Ensuring an integrated and co-ordinated approach to research and development and innovation across NHS Fife ensuring that the organisation remains protected. |

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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| The post holder requires excellent communication and interpersonal skills. These include the ability to develop and maintain good working relationships with colleagues and to always exercise discretion and confidentiality. The post holder is expected to communicate effectively, formally, and informally with a wide range of individuals both internally and externally and will be required to develop effective and efficient systems of communication with relevant Executive Leads. The post holder is expected to analyse and convey complex and potentially contentious data and information in an understandable and professional manner. Additionally, the post holder must be able to balance views of different professionals to deliver in order build consensus and progress areas of responsibility. The network of communication and working relationships for this post is extensive, the key relationships include:**Internal*** Executive Medical and Nurse Directors and other Executive Directors of NHS Fife to keep them briefed and to influence, negotiate and persuade them of the importance and priority of aspects of work programmes.
* Director of Acute Services and their senior leadership team
* Director of the Health and Social Care Partnership and their senior leadership team,
* Senior Medical, Nursing, Pharmacy and AHP teams across the Acute Service and the Health and Social care Partnership.
* Director of Pharmacy and Medicines and their senior team.
* Legal Services Manager and Central Legal Office

**External** * Scottish Government Health Directorate Senior Managers, including Chief Scientists Office, – to maintain knowledge of current developments and thinking in the Government, and to develop relationships which will best serve the Board’s interests.
* Research and Innovation leads in other NHS Scotland Boards – to develop a network of professionals to allow for sharing of develops elsewhere, and to participate in Regional and National work through engagement with the activities of other health boards and rsea4rch nodes and managers
* Local and commercial research companies to advise, review and interpret on all aspects of complex research activity
* East of Scotland Research Ethics service to discuss views on requirements for approvals
* Academic / University Partners- to develop collaborative working, use of NHS Fife resources for research, and conformance to the Research Governance Framework. Local University partners include Queen Margaret University College, Dundee University, St Andrews University, Stirling University, and Edinburgh University.
* Southeast of Scotland Health Innovation Hub (HISES), CSO Innovation team and Innoscot Health to contribute to, and deliver regional and national initiatives on behalf of NHS Fife.

These contacts are often high profile and sensitive requiring diplomatic and influencing skills to motivate and persuade. |

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| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Demands**Sitting at a keyboard for some considerable time - frequently Hand to eye coordination speed and accuracy required for computer use - frequentlyStanding for varying lengths of time if presenting - occasionallyManual lifting and transportation of equipment - occasionallyTravelling between sites in Fife - frequentRequirement to attend meetings and events across and out with Fife – regularly**Environmental and Working Conditions**Use of computer/laptop for long periods of time - frequently Requirement to move and work within sites in Fife – frequently**Mental Demands** This is a challenging role requiring considerable and prolonged original thought, concentration, and creativity. Working with a wide range of internal and external stakeholders, at different levels in organisations, there is a need to utilise a range of influencing and leadership skills.Managing multiple actions and sub-projects, requiring careful project management and organisational skills and the mental agility to manage competing priorities within an unpredictable work pattern.Interpreting, understanding, and consolidating information from a diverse range of scientific, clinical, organisational, and patient perspectives.Understanding people, how to motivate and influence them to participate and contribute their knowledge and expertise.Writing reports and publications in a high standard in accessible language and formats, requiring periods of intense concentration.Preparing and delivering presentations to mixed internal and external stakeholders.Dealing effectively with complex and possibly divergent external interests and prioritiesManaging conflicting views among very senior managers, service users, clinicians, and communities of interest and across complex organisational structures. |
| **Emotional Demands** |
| Accommodating and responding to personal dynamics and the politics of working within a complex organisation – frequently.Negotiating behavioural and cultural change within the complex system of the NHS – frequently.Exposure to highly emotive and clinically sensitive situations with clinicians and managers.Pressure of responding to urgent requests at short notice.Supporting staff to deal with the anxieties associated with change. |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| **Qualifications and experience** * Educated to at least a research Master’s degree or equivalent level of experience with evidence of continual professional development in research and /or innovation
* In-depth professional knowledge in several disciplines relating to the potential application in the conduct of clinical research of extensive legislation and guidance.
* Highly developed specialist knowledge of research, innovation and knowledge management and governance,
* Demonstrable understanding of NHS policy, service/business/strategic planning and operational change management acquired through significant training and experience. Comprehensive and up-to-date specialist knowledge of NHS Scotland Research and Development agenda, policy, and delivery systems
* Knowledge of staff and resource management with ability to plan effective research activities and allocate resources to activities and tasks within the plan.
* Ability to ensure compliance with legal requirements and Board policies and procedures.
* Significant senior experience of change management processes in a complex environment including the identification, delivery and monitoring of qualitative and quantitative benefits.
* Ability to engage stakeholders at a senior strategic level to maximise support and engagement for the changes required across the organisation.
* Ability to negotiate successfully in difficult and complex situations with clinicians and managers and other key stakeholders
* Experience of developing and implementing strategy and of project management at a senior level.
* Experience of having managed teams diverse in both make up and geography.
* Experience of liaising with external agencies and multidisciplinary working.
* Understanding and insight into the national and local challenges of healthcare delivery and specifically those aligned to the portfolio of work.
* Excellent presentation, communication, problem solving and report writing skills
* IT literacy, including practical experience of database management, spreadsheets, and statistical packages.
* Ability to develop effective relationships with a wide range of stakeholders who have differing and sometimes conflicting needs
* Ability to translate highly complex corporate, local, and national strategies into clear objectives, policies and action plans and lead the implementation of these plans for areas of own responsibility, working in partnership with key internal stakeholders to ensure alignment and consistency of approach across the Board.
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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 – RESEARCH, INNOVATION AND KNOWLEDGE ORGANISATIONAL CHART

