#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
| Job Title: Deputy Director  Responsible to: CRF Director  Department(s): Edinburgh Clinical Research Facility (CRF)  Directorate: Research and Development  Operating Division: NHS Lothian University Hospitals Division  Job Reference: L-R&D-ECRF-DD  No of Job Holders: 1  Last Update: Jan 2017 |

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| 2. JOB PURPOSE |
| The post holder is responsible for the direct delivery of a dedicated Clinical Research Facility (CRF) service for NHS Lothian and the University of Edinburgh. He / she directs the operational management, strategic planning and development of Edinburgh’s CRFs (WGH, RIE & RHSC sites) working in partnership with the CRF Director to deliver local and national clinical research strategy as part of NHS Research Scotland (NRS).  The post holder has overall accountability for the management of more than 350 studies annually. Studies involve a broad range of clinical specialities including paediatrics and mental health, and are undertaken in a variety of hospital, community and academic settings.  The post holder will manage staff and be accountable for all aspects of the quality of CRF services, providing professional leadership to the clinical, nursing, administrative, scientific and technical staff groups within the service, ensuring efficient and effective use of resources to maximise research and patient care standards.  The post holder will represent Scotland on the Strategic Planning Team for the United Kingdom Clinical Research Facility (UKCRF) Network, contributing to the UK clinical research agenda by influencing future developments and leading the delivery of national standards for CRFs. |

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| **3. DIMENSIONS** |
| The CRF operates on three hospital sites located in the WGH, RHSC and RIE, as well as supporting the Centre for Dementia Prevention CRF (CDPCRF) on the Little France site. These facilities provide specialised clinical, laboratory and academic research services including five teams of research nurses (one of which operates in the community), genetics & mass spectrometry laboratories, imaging scientists and statisticians.  The post holder is responsible for developing and maintaining the multidisciplinary workforce establishment and provides professional leadership to nursing, administration, laboratory and academic staff, having overall responsibility for approximately 100 posts in total.  The post holder will hold and manage the CRF annual budget (approx £2.3million in financial year 2015/2016) and additional grant and project specific funding totalling approximately £0.5 million annually.  The post holder will represent the CRF Director as required, including attendance at local, national and international research meetings and liaison with the Scottish Government, Chief Scientist Office (CSO), Department of Health (DoH), Wellcome Trust and other external bodies. |

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| 4. ORGANISATIONAL POSITION |
| CRF Director  **Deputy Director**  ***(this post)***  Research Nurse  Manager  Administration  Manager  (U of E)  Quality Assurance  Lead  Nursing Team  WTCRF  Clinical Support  Team  Administration  Team  (U of E)  Core Managers x6  *(Genetics, Epidemiology & Statistics, Education,*  *Mass Spectrometry,*  *Imaging, IA & IT)*  *(U of E)*  Core Teams x 6  (U of E)  **Edinburgh CRF Organisational Chart**  Lead  Research Nurse  (WGH)  Lead  Research Nurse  (RIE)  Lead  Research Nurse  (RHSC)  Nursing  Team  RIECRF  Nursing Team  CCRF  Clinical Support  Team  Biomedical Scientist  Quality Assurance  Manager (CRF/Edinburgh Imaging )  Lead  Nurse for  Phase I /Education  (ALL SITES)  QA Administration Officer  Lead  Research Nurse  (CDPCRF)  Nursing Team  CDPCRF  Clinical Support  Team |

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| 5. ROLE OF DEPARTMENT |
| **Edinburgh Clinical Research Facilities (CRF)**  Edinburgh CRF is a partnership organisation comprising stakeholders and staff from NHS Lothian and the University of Edinburgh. The CRF operates in dedicated clinical research facilities within three NHSL hospitals: the Royal Infirmary of Edinburgh (RIE), the Western General Hospital (WGH) and the Royal Hospital for Sick Children (RHSC). The CRF also supports the research activity of the Centre for Dementia Prevention CRF (CDPCRF) located on the Bio-Quarter site at Little France. In addition, specialist research services are provided within satellite facilities in Edinburgh University’s College of Medicine & Veterinary Medicine (CMVM): the Queen’s Medical Research Institute, Clinical Research Imaging Centre (CRIC) and Brain Research Imaging Centre (BRIC).  The CRF is composed of approximately 100 staff (both NHS and University of Edinburgh contracts) and it supports over 350 clinical research studies annually (academic & commercial) including strictly regulated Phase I/ FIH Clinical Trials. Approximately 9,000 subject visits take place each year (inpatient, outpatient & outreach). The research subject group covers all clinical specialities and includes adult and paediatric patients and healthy volunteers. Research subjects are managed within a variety of NHS and University settings including primary care.  The first of five such centres to be established in Scotland, Edinburgh CRF is accessible to multidisciplinary researchers throughout NHS Lothian, the University of Edinburgh and the national / international research community. The CRF provides a high quality clinical environment in which patients and healthy volunteers can participate in research programmes safely and effectively according to robust, ethically approved protocols.  In July 2011, Edinburgh CRF became a member of the Medicines & Healthcare products Regulatory Agency (MHRA) Phase I Accreditation Scheme. It is the first academic research centre in the UK to achieve this quality standard and is subject to regular compliance checks to maintain this prestigious accreditation status. Edinburgh CRF has established an expert panel of leading clinicians, research managers & statisticians to review early phase and potentially high risk studies on behalf of NHS Lothian (Phase I Scientific Review Committee, PISRC)  NHS Lothian has a national and international reputation for its contribution to biomedical research, and NHS R&D activity is viewed as an essential component of its strategic objectives. Working in conjunction with its academic partners, research charities/organisations and clinical specialities, the Board takes a lead in developing research within Scotland. The CRF has a central role in the delivery of the Board’s R&D objectives through the co-ordination of complex studies, management of research data and the delivery of specialist services within a dedicated environment that facilitates compliance with research governance regulations.  The role of the CRF is to facilitate the translation of basic science knowledge into improved methods of patient care by:   * Providing a co-ordinated, controlled infrastructure underpinned by robust Quality Management Systems, to assist investigators to conduct clinical research safely, efficiently, cost effectively and in compliance with clinical research legislation. * Providing a team of highly skilled qualified research personnel and associated specialist services to support investigators through every stage of their research (Core areas: Epidemiology & Statistics, Imaging, Genetics, Mass Spectrometry, Education and Information Technology). * Providing an MHRA accredited unit in which to conduct early phase clinical trials & First in Human (FIH) studies with access to the skills and expertise required to support these high risk studies. * Leading risk assessment & mitigation processes for Phase I trials on behalf of NHS Lothian Board in order to inform institutional management approval. |

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| 6. KEY RESULT AREAS |
| Operational Management and Strategic Planning   1. The post holder has overall responsibility for the operational management of Edinburgh’s CRFs, including their associated satellite research areas and outreach nursing services. 2. Work with the CRF Director to set short and long term strategic goals for the CRF that are aligned to local and national research priorities. 3. Develop CRF research capacity and capability in response to local and national research strategy, anticipating resource requirements and formulating business plans to fund new initiatives e.g. the expanded Children’s Clinical Research Facility within the new sick children’s hospital and facilities to support research into novel gene therapy treatments.. 4. Collate and analyse CRF activity data, producing regular metrics reports for the Government’s Chief Scientist Office (CSO), Wellcome Trust, NHS Lothian and the University of Edinburgh. 5. In collaboration with the Director, lead in the strategic development of the service including the preparation of grant applications for infrastructure support for national clinical research initiatives.   Financial Management   1. Manage the CRF annual budget of £2.3 million (recurrent) and approximately £500k (non-recurrent), forecasting future funding needs and exploring new funding opportunities. 2. Develop, implement and monitor costing systems that comply with Chief Scientist Office (CSO) requirements (AcoRD - Attributing the costs of health and social care Research and Development), ensuring that NHS Lothian recovers full service support funding and direct research costs for studies that are undertaken in the CRF. 3. Formulate business plans to fund new initiatives e.g. the expanded Children’s Clinical Research Facility within the new sick children’s hospital and facilities to support research into novel gene therapy treatments..   Staff management   1. Provide professional leadership to the multidisciplinary workforce in the CRF, directing appraisal, personal development planning and performance review for the senior management team. 2. As a co-grant holder and member of the UK Clinical Research Facility Network Strategic Planning Team, provide direction and oversee the implementation and delivery of the network’s objectives: national standards for CRF operational management; public engagement in clinical research; training and education; and aligning specific projects to national work stream groups. 3. As a member of the Scottish CRF Network Steering Committee and UKCRF Network Strategic Planning Team, act as primary advisor on Phase I Accreditation for non-commercial clinical research facilities, liaising with the regulatory authority to inform a revised accreditation scheme. 4. As a member of Edinburgh’s Phase I / First in Human Study Review Committee, provide specialist guidance on the risk assessment and management of early phase clinical studies that involve the administration of new drugs to humans for the first time. 5. Direct the CRF team to maintain continuous Phase I Accreditation with the MHRA and engage with academic and industry colleagues to expand and diversify the early phase trials portfolio. 6. Oversee the development and delivery of a comprehensive range of training and education opportunities for multidisciplinary staff, users and students across Scotland, including a new online MSc in Clinical Trials. 7. Provide clinical leadership for the development and implementation of Information Technology systems that support the management of the research portfolio, ensure quality assurance, facilitate financial management and coordinate subject scheduling for CRF studies. 8. Establish a system for user involvement that informs service improvements for patients, researchers and the public. |

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| 7a. EQUIPMENT AND MACHINERY |
| Desktop and laptop computer.  Desktop and network printer.  Document Scanner / Document Shredder / Photocopier  Telephone / Fax Machine / Teleconferencing Equipment  Videoconferencing Equipment / Power Point Projector / Web cam / Digital Camera  Ultra low temperature freezers (-40oC and -80oC) and associated auto-dialler alarm system (post holder is called out in the event of a mechanical failure in order to salvage research samples and ensure their safe transfer under optimal conditions to an alternative freezer. Requires interrogation of auto-dialler to determine location and fault of malfunctioning freezer.)  ADT Security System (CRF Intruder Alarm)  The post holder is responsible for scoping and purchasing new equipment for the CRF and advising researchers on the type and specification of equipment required for their studies. The post holder is required to have awareness and working knowledge of a variety of clinical and research equipment. |
| **7b. SYSTEMS** |
| IT Use of Share Point electronic document management system  Creation and maintenance of electronic spreadsheets and databases  Development of study tools and monitoring systems.  Maintenance up-to-date information on the progress of all research studies  Ensuring secure back up, storage and archiving of electronic study data.  TRAK – hospital information management system  Empower / SSTS HR system – electronic staff records for absence, training, holidays  DATIX Intranet – Incident Reporting  Internet and Intranet – Personal development and business use.  Use of CRF ManagerTM patient and room scheduling system to record / report occupancy levels  CRF ManagerTM (a bespoke suite of IT applications to record research activity, schedule subject visits and produce activity reports)  CRF Asset Register to maintain an inventory of CRF equipment and associated maintenance contracts, service records  Online scientific and medical literature archives e.g. Pubmed |

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| 8. ASSIGNMENT AND REVIEW OF WORK |
| The post holder has a significant degree of freedom to act in terms of the management and delegation of his / her workload.  The post holder will exercise a considerable degree of autonomy in relation to the setting of professional priorities within nationally agreed strategic frameworks and local clinical research policies.  In conjunction with the CRF Director, the post holder will set annual performance objectives and these will be reviewed in accordance with NHS Lothian performance management systems. |

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| **9. DECISIONS AND JUDGEMENTS** |
| Grant approval for clinical research studies to be undertaken in the CRF and allocate resources appropriately.  Make autonomous high level decisions across a range of complex strategic issues including service modernisation, workforce planning and the use of recurrent and non-recurrent funding allocations e.g. authorise the clinical design and staff establishment of the expanded Children’s CRF in the new sick children’s hospital.  Interpret long-term government strategy alongside local / national trends in research activity and formulate strategic objectives for the CRF that are aligned to the national clinical research agenda e.g. securing & maintaining Phase I Accreditation with the Medicines and Healthcare products Regulatory Agency (MHRA).  Develop and refine CRF operational and research policy in response to the evolving needs of the service e.g. implementing a Phase I / First in Human Scientific Review Committee to risk assess early phase clinical trials and high risk experimental medicine studies  Recognising and acting upon staff performance issues that necessitate education, support, counselling or disciplinary action.  Recognising and acting upon breaches of research governance legislation, responding appropriately and escalating action as required. This may involve launching a formal investigation into incidences of suspected fraud or research misconduct that involve senior clinical academic professionals.  Acting in the research subjects’ best interests to ensure their rights are upheld, when overseeing the management of clinical research studies undertaken in the CRF. Acting to suspend or terminate approval for continued use of the CRF as necessary.  Using expert clinical skills and research knowledge to design and assess research protocols, addressing issues of organisational risk, scientific validity, resource utilisation and practical feasibility.  Provide expert scientific and managerial input to NHS Lothian’s Research Management Committee.  Provide guidance to investigators on Research Governance, involving interpretation of complex policy and legislation.  Manage his/her time effectively to meet competing demands, ensuring that work is prioritised and that outcomes are delivered timeously. |

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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB | |
| Leading an organisation that comprises multidisciplinary staff from two stakeholder institutions (NHS Lothian & the University of Edinburgh) and operates across three hospital sites.  Leading the development and delivery of long-term CRF strategic goals against a backdrop of dynamic national healthcare and research policy.  Working to tight deadlines, often in response to unexpected requests for written reports or meetings at very short notice.  Making critical decisions on the use of recurrent and non-recurrent funding streams to ensure that the CRF’s strategic objectives are delivered on time and within budget.  Implementing and maintaining quality management systems that are responsive to increasingly stringent research legislation.  Securing stakeholder engagement with the implementation of systems that are politically sensitive and involve management of change.  Raising awareness of CRF resources and services among the local, national and international research community.  Promoting a shift in culture that encourages long established researchers to relocate their studies to the controlled environment of the CRF, thereby facilitating compliance with clinical research governance.  Responding to fast evolving R&D policy, acting to ensure that CRF services, systems and capacity are appropriate to meet the needs of the local and national R&D agenda  Adapt to a constantly and rapidly changing environment at local and national levels and influenced by changing national policies and regulations  Make complex judgements based on expert and wide-ranging knowledge and interpretation of specific situations.  Ensure high quality research receives a high profile and increase funding of research support in the Region. |

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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| The post holder is required to deploy advanced communication skills with a range of internal and external stakeholders e.g. Chief Scientist Office (CSO), National Institute for Health Research (NIHR), Medicines and Healthcare products Regulatory Agency (MHRA), National Office for Clinical Research Infrastructure (NOCRI), UKCRF Network and internal partnership organisations.  The post holder will implement a communication strategy to develop awareness of Edinburgh CRF’s strategic plan and key objectives and to secure involvement from partner organisations and stakeholders. Specific communication skills required include the ability to:   * chair meetings effectively * persuade, influence and negotiate in order to reach consensus, and secure involvement of colleagues in initiatives * facilitate workshop and focus group discussions * write reports, articles and papers to publication standard * present complex/specialist information at internal and external meetings and conferences * present and brief groups of internal and external stakeholders with complex information which may challenge existing practices. |

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| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Demands:**  Prolonged periods of VDU exposure on a daily basis.  **Mental Demands:**  The work pattern is often unpredictable and frequently involves having to re-schedule appointments at short notice and stay late to cover prolonged studies and meetings in the facility.  There is a frequent requirement to work to very tight deadlines in order to meet academic, financial and commercial project targets.  Frequent prolonged periods of concentration are required on a daily basis to assess, interpret and cost study protocols and business cases. The post holder spends long periods collecting complex data for weekly, monthly and annual reports involving some statistical analysis and database input.  There are constant interruptions whilst reading / writing reports. Frequent enquiries from internal and external departments requiring information and advice with no prior warning. Many highly stressful meetings requiring tact and difficult decision making re: budgets, facilities and manpower solutions.  **Emotional Demands:**  Occasional dealings with complaints, incidents (clinical and non-clinical), staff support and counselling and very occasional contact with distressed patients and relatives.  Rare contact with irate or abusive staff in unprofessional circumstances that requires tact and diplomacy.  Providing support to staff and patients who are involved in studies that offer the only possible treatment hope/option in end of life situations.  Due to the confidential nature and highly sensitive content of some research projects, there is a frequent requirement to sign confidentiality agreements and financial disclosure forms with pharmaceutical companies.  Undertaking business critical regulatory inspections that have implications for the CRF’s future compliance and sustainability.  Exposure to clinical information at times may be distressing.  **Environmental & Working Conditions:**  Day to day requirement to travel between hospital and university sites in Lothian.  Frequent requirement to travel throughout the UK for meetings that often involve an overnight stay.  Occasional requirement to travel internationally to conferences and meetings.  Occasionally called out in unsocial hours in event of triggered security alarm or freezer failure. |

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| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| Current registration with the Nursing and Midwifery Council (NMC) or other equivalent health care professional body.  Educated to Masters level in a clinical or life sciences related subject  Up to date training in ICH GCP (International Conference on Harmonisation Good Clinical Practice)  Experience of working at a senior management level with specialist knowledge of clinical research across a broad range of clinical conditions and treatment modalities  Proven leadership qualities and ability to work effectively as part of a team  Highly developed working knowledge of regulatory frameworks and legislation governing the conduct of clinical research. These include but are not restricted to: the Research Governance Framework for Health and Community Care, Medicines for Human Use (Clinical Trials) Regulations, Adults with Incapacity (Scotland) Act, Data Protection Act, Governance Arrangements for Research Ethics Committees and Human Tissue Acts.  Experience of leading preparation for regulatory inspections including MHRA Phase I Accreditation.  Working knowledge of UK clinical research infrastructure.  Excellent communication skills (oral, written & presentation) with proven ability to write reports and present complex information to a variety of senior stakeholders  Evidence of personal, professional and academic development.  Time management and organisational skills with ability to prioritise workload and meet tight deadlines.  Proactive, self-motivated with ability to motivate and influence others, demonstrating well developed negotiation skills, diplomacy and good judgement.  Proficient in the use of Microsoft Office applications |

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| **14. JOB DESCRIPTION AGREEMENT** | |
| Job Holder’s Signature:  Head of Department Signature: | Date:  Date:  Jan 2017 |