|  |
| --- |
| JOB IDENTIFICATION |
|  Job Title: Research & Development Co-ordinatorResponsible to : Senior Research AdvisorDirectorate: Medical DirectorateOperating Division: NHS Ayrshire & Arran Job Reference:No of Job Holders: 1 Last Update: 26th May 2021 |

|  |
| --- |
| 2. JOB PURPOSE |
| The post holder will be a core member of the Research & Development (R&D) Team with a specific remit to facilitate commercial clinical trial or non-commercial clinical research trials or projects in line with the R&D Strategy and the Chief Scientist Office (CSO) recognised priority areas. The post holder will facilitate activity which is compliant with the statutory legislation and the standards required to meet the UK Policy Framework for Health and Social Care Research 2017 |

|  |
| --- |
| **3. DIMENSIONS** |
| * Provide support to all geographical and service areas throughout NHS Ayrshire & Arran (NHSA&A).
* Work with NHS Research Scotland Permissions Coordinating Centre (NRSPCC) to progress national projects within Scottish Government set time deadlines.
* Support NHSA&A research/evaluation active staff and external investigators intending to access NHSA&A patients, staff, clinical and non-clinical service areas.
* Support all internal and external investigators including those from commercial companies, Clinical Research Organisations and academics through activities associated with the development and initiation of all types of research/evaluation activity such as securing a favourable ethical opinion and R&D management approval within Scottish Government set time deadlines.
* Support the Senior Research Advisor in the procedures for identifying all ideas and innovations and facilitate the management of these in line with NHS Ayrshire & Arran Intellectual Property Policy.
* Support research teams through any internal and/or external auditing and monitoring of the project including Medicines and Healthcare Products Regulatory Authority (MHRA) inspections.
* Facilitate the dissemination of progress reports and the results of all research trials/projects/evaluations.
* Responsible for ensuring that the electronic and paper R&D records are accurate and complete.
* Responsible for providing accurate and complete data on research/evaluation projects to the Senior Research Advisor and Heads of relevant service areas as required.
* Responsible for working with the Support Accountant to ensure that they are provided with the relevant information to inform the costing of projects and agreed costs are reimbursed.
* Attend Service Research Strategy groups as appropriate to maintain communication between the R&D Team and Research/Evaluation teams.
* Attend relevant meetings to facilitate the progression of cancer clinical trials in NHSA&A.
* Work with Research Nurses and Trials Facilitators on a daily basis to maintain communication and facilitate the progression of eligible trials in NHSA&A.
* Attend R&D team meetings and others on direction from the Senior Research Advisor
* Attend project steering group meetings as and when required.
 |

|  |
| --- |
| 4. ORGANISATIONAL POSITION |
| Appendix 1  |

|  |
| --- |
| 5. ROLE OF DEPARTMENT |
| * The team is responsible for the management of high quality research and development in NHSA&A in line with strategic direction and statutory legislation. The team is responsible for the effective management of CSO funds, Network funds, commercial trial revenue and non-commercial grants. The team is also responsible for developing the infrastructure and culture in which research in NHSA&A will continue to grow and contribute to evidence-based practice including ensuring the NHS benefits both intellectually and financially from any inventions or new knowledge by the appropriate protection and exploitation of intellectual property opportunities. The team is part of the Medical Directorate and works alongside Information Governance and Risk Management. The team works in partnership with the National Research Network managers to increase Scottish patient’s access to clinical trials and provide patient choice
 |
| 6. KEY RESULT AREAS |
| The post holder will be a key member of the R&D Team and will:* Develop effective working relationships with clinical and non-clinical service areas throughout NHS Ayrshire & Arran to promote research/evaluation and provide guidance/training 1-1 and group using Powerpoint and example paperwork to ensure that potential researchers/evaluators are educated on their responsibilities in relation to UK Policy Framework for Health and Social Care Research 2017 to meet the legislative requirements of the European Union Directive for Clinical Trials, Data Protection, Freedom of Information and Health and Safety Acts as appropriate.
* Develop effective working relationships with internal and external researchers/evaluators wishing to access NHSA&A resources in respect of R&D/ Evaluation Projects and support them through the ethics application and management approval process in addition to providing advice and training. in relation to adherence to national and local guidelines and policies as appropriate.
* Advise, facilitate and support internal and external researchers/evaluators undertaking projects to ensure consistency of approach in information required, data prepared and compliance with the R&D Strategy, Internal Policies, the UK Policy Framework for Health and Social Care Research 2017and the EU Directive.
* Advise, facilitate and support internal and external researchers on methodological issues and efficient project planning by providing contacts for statistical analysis and access to research training i.e. sampling, data tool design, database development, data collection, data analysis, report writing and questionnaire design.
* Responsible for the preparation, allocation and distribution of Project Reviews/ Project Amendments to the relevant support service areas as a key part of the management review process for projects. Ensure that any issues raised by service areas are brought to the immediate attention of the researchers, making sure that these issues are addressed and resolved in a timely and efficient manner prior to the researcher receiving management approval to undertake the project within NHSA&A. This process must be completed to comply with Scottish Government set time deadlines.
* Ensure all research projects are correctly costed and budgets in place to ensure the project is cost effective and value for money by liaising with the Finance Department and Research Teams and identifying where researchers can submit a funding application to the R&D Committee and assisting with this process by ensuring the correct information is collated and submitted.
* Responsible for accepting and facilitating the management approval of projects submitted via NHS Research Scotland Permissions Coordinating Centre (NRSPCC) on the Scottish National R&D Application (SReDA - an internet based National database) to comply with Scottish Government set time deadlines.
* Compile, detailed accurate reports on the status of all NRSPCCprojects , highlighting any discrepancies in dates and timescales from the metrics issued by NRSCC. This information is required by the Senior Research Advisor to ensure accurate feedback to the CSO.
* Responsible for database population and compilation of reports using national databases but not limited to SReDA, EDGE or CPMS systems.
* Actively assist in the development of the Scottish Research and Development database (SReDA) to ensure recording in line with national requirements and reporting needs of the organisation whilst identifying areas requiring improvement and liaising with SReDA Coordinator.
* Highlight the importance in maintaining confidentiality and security to researchers/evaluators providing training and advice especially when projects may involve reviewing or screening the identifiable personal information of patients, service users or any other person to ensure they are aware of and comply with NHSA&A Information Governance and Information Technology Security Policies and National Legislation.
* Responsible for the review of site-specific information with regard to local issues e.g. ensure the Principal Investigator has appropriate research experience/training, adequacy of local facilities to conduct research, issues regarding consent, accuracy of local study paperwork to ensure that the service is able to support/host the research. If any areas of concern are identified liaise with the researchers through advice/training as appropriate until these issues have been resolved.
* Responsible for establishing the employment contract status of external researchers coming into NHSA&A ensuring the researcher has submitted the correct paperwork to allow the compilation (where required) of the relevant documentation e.g. National Research Passport, National Honorary Research Contract, Letter of Access, Confidentiality Agreement, Disclosure Scotland Checks and liaise with Human Resources as required.
* Responsible for communicating with the West of Scotland SCRN office in the Beatson Oncology Centre with regard to SCRN Trials running in NHS&A. Ensuring all paperwork is received in a timely manner, distributed appropriately for service review prior to trials being approved and that all parties are kept updated with the progress of R&D Management Approval.
* Communicate daily with the Cancer Clinical Trials Research Nurses and Trial Facilitators to support the management review of cancer clinical trials and facilitate the progression of trials by linking with the appropriate clinicians to ensure that all parties are aware of any developments and any subsequent actions required.
* Responsible for liaising with the Central Legal Office (CLO), SCRN and external agencies with regard to Clinical Trial Agreements, Material Transfer Agreements and Memorandums of Understanding to ensure the required agreements are in place before a trial starts.
* Responsible for working with Masters and PhD Students to develop/coordinate their projects through the R&D Management approval process identifying any service area issues/concerns and negotiating with these areas until resolved. As well as working with internal service areas, this also includes communicating with the researcher’s University Supervisors and on occasion the Governance Department of the University.
* Liaise with the West of Scotland Research Ethics Committee to ensure that projects are submitted for ethical review and work with researchers to address any issues that are raised.
* Responsible for liaising with the Medicines and Healthcare Products Regulatory Authority (MHRA) to ensure all trials have the relevant authorisations in place prior to commencing.
* Responsible for providing information in relation to any MHRA monitoring and auditing activities or site visits within NHS Ayrshire and Arran. This may involve gathering project related data and/or consulting/coordinating with activity areas regarding service area visits.
* Monitor and input data against projects activity using national databases but not limited to SReDA, EDGE Database (Study coordination database for cancer studies) and CPMS (Study recruitment management system)ensuring that progress and final reports are requested, received and disseminated whilst ensuring any issues are identified and dealt with appropriately.
* Support and actively assist the Senior Research Advisor in the procedures for identifying all Intellectual Property and facilitate the management with the internal and external researcher/research team in line with NHSA&A Policy. Intellectual Property (I.P) is the invention of something new by staff which can be exploited within the healthcare system. It can take the form of a new product or an adaptation to an existing product.
* Collate and provide project updates to the Senior Research Advisor weekly, or as and when required. Project updates will also be provided to the Project Team on a weekly basis
* Assist in the monitoring and auditing of research projects sponsored by NHS Ayrshire and Arran this includes measuring compliance, checking record keeping and protocol adherence of projects in line with current local and national guidelines. If any areas of concern are identified make sure that these issues are addressed and resolved in a timely and efficient manner, using this information to inform learning for other teams.
* Collate and compile data for the CSO, and annual finance report ensuring that the information is accurate in accordance with the CSO guidelines.
* Liaise with the UK Clinical Research Networks (UKCRN) e.g. Stroke, Diabetes, Paediatrics, Mental Health. Identifying with the Research Nurses possible projects that have a potential to open in NHS Ayrshire and Arran.
* Produce Standard Operating Procedures (SOPs) for all relevant activities within the R&D office with guidance provided by the Senior Research Advisor updating when necessary and ensure R&D staff are aware of and adhere to the SOPs.
* Responsible for facilitating feasibility assessments for research/evaluation projects as necessary. Ensure that all issues raised through such assessments are brought to the attention of the relevant researchers, Senior Research Advisor and Service Areas.
* Provide advice, guidance and support to the Research Nurses and Trials Facilitators on a day-to-day basis on a variety of topics e.g. project amendments, navigating the electronic project files, ensuring all required authorisations are in place and all local paperwork is up-to-date and accurate for each project.
* To attend/rotationally chair fort nightly Project Team meetings providing updates and information to other team members as required.
* Communicate with the Research Groups within NHSA&A to ensure that they are kept up-to-date with the latest developments in Research and Development via Athena, email and attendance at service area meetings.
* Ensure all R&D data on Athena i.e. guidelines/procedures, activity and information on how to apply for ethics and R&D Management Approval, is accurate and up-to-date in line with local and national guidance.
 |
| 7a. EQUIPMENT AND MACHINERY |
| Laminator - the post holder will use this to preserve documents/posters as required.PC - The post holder will use this on a regular day-to-day basis, as the use of a computer is essential in carrying out their duties e.g. Internet, Word, Access, Excel, PowerPoint, Microsoft Outlook, Athena.Photocopier - The post holder will duplicate reports and other paper based information.Telephone – The post holder will use this on a day-to-day basis, as the use of a telephone is essential in carrying out duties.Scanner – The post holder will use this to convert pages of text/drawings to electronic format for electronic transmission and to attach to the database.Laptop computer – used to take to meetings when providing presentations.Powerpoint projector – used at meetings alongside the laptop computer when providing presentations. |
| **7b. SYSTEMS** |
| Paper and electronic records relating to project management including* Management approval records and template letters and emails
* SReDA Database for Research Projects (National database , internet based – inputting data, updating records and producing reports)
* EDGE Database (Study coordination database for cancer studies) and CPMS (Study recruitment management system)
* Standard Ethics application form (Internet based)
* Project Files (creating and updating)
* Clinical Trial Agreements, indemnity agreements with external organisations
* Standard Operating Procedures (SOPs) (creating and updating)
* Table of New Projects/Pending/Update list (update list of projects received in R&D and current status of projects pending on a fort nightly basis)

Electronic data storage e.g. Internet, Word, Access, Excel, PowerPoint |

|  |
| --- |
| 8. ASSIGNMENT AND REVIEW OF WORK |
| The post holder will be responsible to the Senior Research Advisor and expected to manage own workload within agreed timescales.Initial review will occur on a weekly basis but the frequency may be reduced once the post is established.The post holder will have objectives set in conjunction with the Senior Research Advisor. |

|  |
| --- |
| **9. DECISIONS AND JUDGEMENTS** |
| The post holder is responsible for ensuring delivery on the key result areas, working with a notable degree of autonomy, employing effective time and workload management skills towards achieving the broad plans and objectives agreed in advance with the Senior Research Advisor.The post holder will be required to make decisions on a daily basis using their own initiative, skills and knowledge regarding workload, project timescales and research legislation. Typical judgements made in the course of the job include:* Liaise with NHS Research Scotland Permissions Coordinating Centre (NRSPCC) to ensure that the required project paperwork is available prior to the commencement of the national/local review process.
* Identify when incorrect dates and timescales have been recorded and highlight this to NRSPCC.
* Negotiating with internal and external researchers/evaluators to establish what is required from them and when in terms of paperwork/dates.
* Communicate with external agencies and the Central Legal Office (CLO) to negotiate contracts and agreements.
* Amending paperwork so that specific information is more easily obtained/given.

The post holder will recognise when it is appropriate to seek further expertise.The post holder will also recognise any possible intellectual property opportunities and bring this to the attention of the Senior Research Advisor  |

|  |
| --- |
| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| * To negotiate with internal and external research/evaluation teams of various expertise and with diverse research interests.
* To motivate and assist investigators and support services to complete the necessary documentation.
* To facilitate the management of a number of projects at any given time and to meet the national target timescale.
* To co-ordinate a number of activities e.g. completing IRAS application, negotiating service area/clinical trial agreements, ensuring paperwork is up-to-date and compliant with current guidelines, ensure costs have been identified and funds available prior to the initiation of a project
* To keep knowledge up-to date incorporating the constant changes and developments in research legislation, rules and procedures that must be adhered to and communicating these to researchers and colleagues.
* The post holder receives work from a variety of sources on a daily basis and must assimilate and understand this information whilst prioritising and reprioritising the workload to achieve completion within the strict timescales of the Scottish Government and NRSPCC; this requires frequent intense periods of concentration whilst managing interruptions and additions to the workload.
* Achieving a balance between the demands of new and ongoing research activity within existing limited resources.
* Negotiating/dealing with researchers/evaluators who may be emotional/stressed and act to resolve issues.
 |

|  |
| --- |
| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| InternalR&D TeamCancer Trials TeamClinical and Non-Clinical Support Services e.g. Medical, Surgical, Woman and Children and Diagnostic Services Directorates, GPs, Community Health Partnerships, AHPs, Addiction Services, Finance, Human Resources, Health and Safety Departments. FinanceInformation TechnologyInformation GovernanceResearch Active ProfessionalsHealthcare Quality, Governance & Standards Unit ExternalInvestigatorsNHS Research Scotland Permissions Coordinating Centre (NRSPCC)West of Scotland Ethics CommitteeScottish Cancer Research NetworkUK Clinical Research Network (UKCRN)Peers in other NHS organisationsScottish Health Innovations Ltd & associated companies e.g. Kare Orthopaedics, manufacturers Monitoring Bodies contracted to undertake auditsChief Scientist OfficeCentral Legal OfficeUniversitiesMedicines and Healthcare Regulatory Authority (MHRA)Funding bodies – non commercial and commercial e.g. Cancer Research UK, Astra ZenecaIndependent StatisticianExternal Trainers |

|  |
| --- |
| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical Skills/Effort*** Requirement to use VDU equipment for approximately 80% of the working day, as use of a computer is essential in carrying out duties.
* Driving skills required for travel to various NHS Ayrshire and Arran sites to attend meetings.
* Requirements for speed, accuracy and advanced keyboard skills.
* The post holder must be physically fit to carry, photocopy and file research/evaluation files which can weigh up to several kilos. Will also be required to transport, set-up and use laptop computer and PowerPoint projector for presentations at meetings.

**Mental Effort/Skills*** Frequent high levels of concentration are required for up to 2 hours at a time with frequent interruptions, along with prolonged PC use.
* Frequent requirement for high levels of intense concentration when completing Research Initiation Checklists whilst still receiving interruptions from phone calls and enquiries from colleagues.
* Prioritising work within tight timescales.
* Frequent requirement for intense concentration when preparing project updates, attending meetings and meeting with researchers/evaluators.

**Emotional Effort/Skills*** Dealing with challenges and personalities internally and externally and other conflicting demands, which may impact on therole.
* Even with the best co-ordination skills, the pressures of deadlines i.e. submission dates, meetings, objectives and data collection can be difficult to achieve. Due to the ad hoc nature of the job, staff are encouraged to contact the Research & Development team for advice and support, and sometimes what can start out to seem like a simple query can lead to a complicated problem. This in turn can encroach on valuable time which has been co-ordinated for other activities. Having to juggle several different factors within the role can be stressful and require reassessment of time management several times.

**Working Environment*** Frequent requirement for sitting in a restricted position for a substantial proportion of the working day e.g. 2 hours at a time. Eye strain and repetitive strain injury are occupational health hazards.
 |

|  |
| --- |
| 13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB |
| * Educated to Degree level or equivalent specialised research/evaluation administration experience and knowledge.
* Knowledge of statutory requirements in relation to Health & Safety, Data Protection and Freedom of Information.
* Knowledge of the UK Policy Framework for Health and Social Care Research 2017.
* Experience of working in a healthcare environment.
* Understanding of the research and evaluation process.
* Excellent communication, negotiating and interpersonal skills.
* Ability to work on own initiative within predefined parameters.
* Ability to work within teams and independently.
* Excellent time management skills with the ability to deliver to tight deadlines.
* Should have excellent IT skills.
 |

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

|  |
| --- |
| Head of Research & Development 1 x WTE1 x WTE Senior Research Advisor 1 x WTE**Lead R&D Facilitator** **2.0 WTE** R&D Co-ordinator1 x WTE- **This post**R&D Support Officer 1 x WTELead Clinical Trials Nurse 1 x WTE Research Nurse Clinical Trials Nurse Band 6 Band 66.2 WTE 2.3 WTE Research Nurse Band 5 0.6 WTE0.6 WTE vacancy  |