



JOB DESCRIPTION

1. JOB IDENTIFICATION

Job Title: R&D Commercial Lead

Responsible to: Head of Research Governance

Department(s): Research & Development (R&D)

Directorate: Department of Public Health and Health Policy

Operating Division: Corporate

No of Job Holders: 1

Last Update: January 2022

2. JOB PURPOSE

On behalf of all research active health boards in NHS Research Scotland (NRS), work as NHS Lothian's R&D Commercial Lead, responsible for the generic governance review of commercially funded multi-centre research applications in Scotland.

Working collaboratively with the NRS Generic Review Manager, deliver a comprehensive research governance review system for clinical research projects undertaken within NHS Lothian.

Review and negotiate a wide range of budgets contracts and agreements connected with commercial research carried out throughout NHS Scotland, providing legal advice and ensuring that health boards meet all of their statutory obligations.

Be responsible for delivery of a robust and responsive local governance review system for research amendments.

Work in close collaboration with staff from the Chief Scientist Office (Scottish Government) to implement national policy in this area.

3. DIMENSIONS

Local delivery of R&D is through NHS Health Boards grouped into NHS Research Scotland (NRS) 'nodes', each made up of several Health boards, centred on the teaching hospitals in Aberdeen, Dundee, Edinburgh and Glasgow. NHS Lothian and NHS Borders make up the South East Scotland node.

Work in close collaboration with the NHS Research Scotland Permissions Coordinating Centre (NRSPCC) located in NHS Grampian.

This lead role combines oversight of all commercial generic research governance reviews undertaken on behalf of NRS (for Lothian Health Board and up to 10 other Scottish Health Boards in the 4 NRS 'nodes'), and commercial local research governance reviews for research projects taking place within NHS Lothian. The number of commercial research projects amounts to approximately 900 reviews per year.

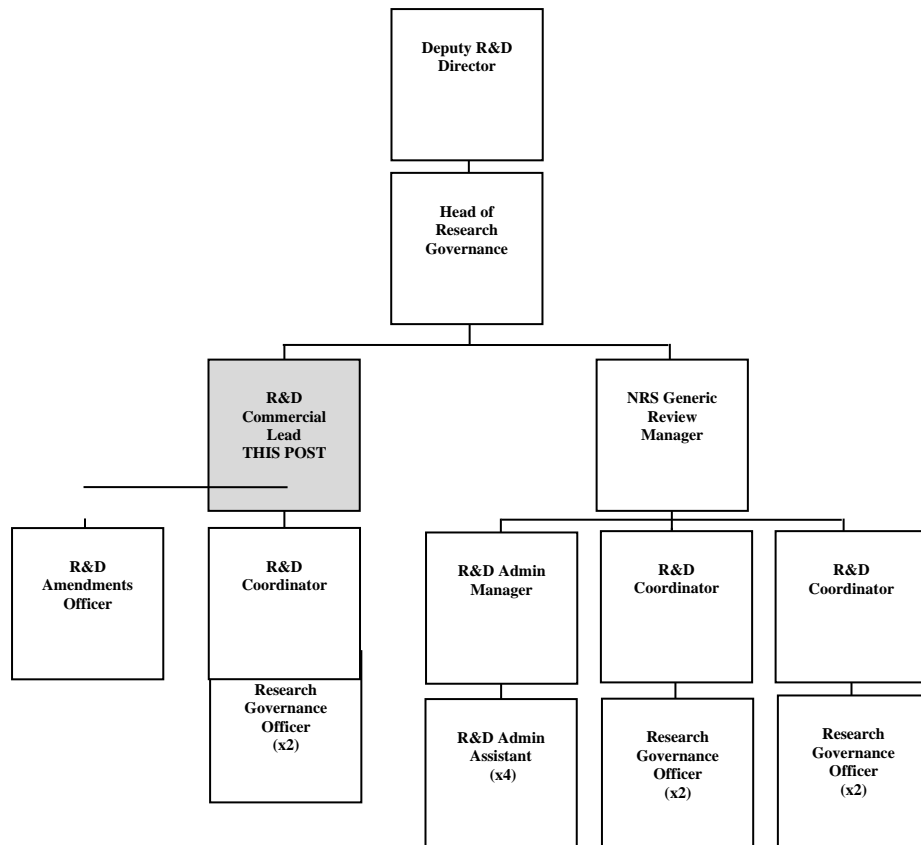
Providing advice regarding all aspects of hosted commercial research to approximately 1,800 NHS research staff (clinicians, nurses, support staff across all disciplines), 100 senior university academics and 200 commercial clients.

Reviewing and negotiating contracts and budgets for studies with contract values ranging up to £500,000, which includes contracts that generate an annual commercial income in excess of £3,000,000 for NHS Lothian.

Direct line management of an R&D Coordinator and a R&D Amendments Officer in NHS Lothian, with indirect line management responsibility for 2 Research Governance Officers.

The post holder is employed within NHS Lothian and there may be a requirement to work flexibly across Lothian to meet service demands.

4. ORGANISATIONAL POSITION



5. ROLE OF DEPARTMENT

The Academic and Clinical Central Office for Research and Development (ACCORD) is comprised of research management staff from NHS Lothian and the University of Edinburgh College of Medicine and Veterinary Medicine. These staff are co-located within the Queen's Medical Research Institute where they provide a joint office for clinical research management on behalf of NHS Lothian and the University of Edinburgh. ACCORD provides the following services:

1. Bidding for, managing and reporting on the R&D infrastructure funding received by NHS Lothian from the Scottish Government (currently £10,000,000 per annum).
2. Implementing Research Governance initiatives and delivering the Local Research Governance Implementation Plan across NHS Lothian.
3. Implementing the NHS Lothian R&D strategy, to inform future development of policy.
4. Keeping up-to-date records of all research activity ongoing within NHS Lothian, liaising closely with support departments to report research activity levels and facilitate their full participation in R&D.
5. Ensuring Investigators and NHS Lothian are fully compliant with all legal responsibilities associated with hosting Clinical Trials, and other clinical research.
6. Facilitating good quality, well managed research; providing support and building systems which encourage a broad and dynamic research culture within NHS Lothian.
7. Facilitating the building and development of regional research networks, encouraging well-governed research collaborations and supporting state-of-the-art clinical research facilities.
8. Managing commercial research, negotiating appropriate contracts with commercial (and non-commercial) partners, administering research income and ensuring financial probity.
9. Identifying, managing and commercialising NHS Lothian Intellectual Property in collaboration with Scottish Health Innovations Ltd and Health Innovation South East Scotland.

NHS Research Scotland (NRS) is a partnership between the Chief Scientist Office (CSO) and the Health Boards in Scotland. Its aim is to agree and implement national policy and to deliver greater efficiency to the NHS R&D and research ethics service through Pan-Scotland working. NRS comprises the 11

Research Active NHS Scotland Boards who have signed up to the principles of NRS. NRS gives approval for many hundreds of new eligibly and commercially funded studies every year.

The Chief Scientist Office (CSO) is the part of the Scottish Government Health Directorates which supports and promotes high quality research aimed at improving the quality and cost-effectiveness of services offered by NHS Scotland and securing lasting improvements to the health of the people of Scotland. CSO supports research initiated by the research community in Scotland and advises the Scottish Government on how research contributes to improvements in health and healthcare.

6. KEY RESULT AREAS

Research Governance Reviews (30%):

1. Responsible for the delivery of generic governance reviews for commercial research taking place in NHS Scotland (on behalf of NHS Lothian and other Scottish Health Boards), ensuring that projects are robustly assessed and R&D permission granted within Chief Scientist Office (CSO) target timelines.
2. In collaboration with the NRS Generic Review Manager, direct the local review of clinical research studies that are submitted to NHS Lothian. Identify any patient welfare, corporate risk, and sponsorship or resource issues relating to the study protocols, ensuring that appropriate scientific review is undertaken and that studies are safe, practical and financially viable.
3. Responsible for the delivery of an NHS Lothian R&D system for tracking, processing and approving amendments to research projects, ensuring review and approval by the wider Research Governance team is completed in a timely manner.
4. Deputise for the NRS Generic Review Manager during periods of absence.

Contracts & Budgets (40%):

5. Ensure that all commercial research projects are correctly costed to nationally acceptable standards, using the interactive costing tool (iCT), and that the contracts finalised with commercial partners generate significant income to the Board (it is expected that the post-holder will negotiate individual contracts up to the value of £500,000 each). Where commercial research project are multi-centre, budget negotiations, using the iCT, are on behalf of NHS Scotland i.e. (i.e. 'single cost for Scotland').
6. Responsible for the review, negotiation and finalisation of contractual and financial terms for hosted commercial clinical trials on behalf of NHS Lothian, ACCORD and studies allocated via NRS ensuring that local and national Standard Operating Procedures and Work Instructions are followed. This is done in consultation with the Principal R&D Manager, the R&D Contracts Officer and the Central Legal Office (CLO), where required, using knowledge and understanding to determine which model agreement is most suitable for a research study. The workload is varied but approximately 20-30 negotiations can be going on at any one time.
7. Identify and reduce wherever possible any potential risks or liabilities falling to NHS Lothian under hosted commercial research contracts. Ensure that appropriate indemnities are granted by a commercial partner under the terms of these contracts.
8. Ensuring that researchers are made aware of their responsibilities under commercial research contracts, and any other contractual and/or financial terms relevant to their research (e.g. rights in relation to publication or the management of intellectual property). This will need to be delivered on a case-by-case basis to individual or small groups of researchers as all contracts will be different.

Policy and service development (10%):

9. Be proactive in identifying the need for, formulating and implementing Standard Operating Procedures (SOPs), Work Instructions (WIs) and policies in relation to areas of own work (e.g. management of research income and contracts).
10. Ensure that all available local and national SOPs and WIs are followed in relation to study reviews and negotiations that are undertaken on behalf of NHS Lothian, NRS and other Health Boards.
11. Be proactive in marketing NHS Lothian's capability and capacity to undertake commercially sponsored research and build long-term relationships with external commercial partners in order to generate more income to the Board.
12. Participate in national working groups to advance commercial research governance systems that will expedite management approval for multi-centre studies undertaken in Scotland and elsewhere in the UK.

Human resources (10%):

13. Provide line management to Research Coordinator, Research Governance Officers and R&D Amendments Officer, including setting and delegating workload, providing appropriate training, reviewing performance, dealing with grievance and attendance issues, setting objectives and facilitating personal development. Training in the use of the iCT may extend to the wider NRS community as well as to internal R&D staff.
14. To support NHS Lothian's values of quality, teamwork, care and compassion, dignity and respect, and openness, honesty and responsibility through the application of appropriate behaviours and attitudes.

Information resources (10%):

15. Ensure that study budget and commercial research metrics are collected in SReDA and collated in a timely manner to meet report returns to NRS and the CSO. This will require manipulating and generating complex spreadsheets detailing financial, recruitment and other summary metrics to meet local, NRS and Chief Scientist Office reporting schedules, analysing data and preparing written reports and presentations.

7a. EQUIPMENT AND MACHINERY

The following are examples of equipment which will be used when undertaking the role.

The post-holder will use a personal computer on a daily basis (desktop computer and/or laptop computer).

The post-holder will use other pieces of standard office equipment (telephone, printer, scanner and photocopier).

Note: New equipment may be introduced as the organisation and technology develops, however training will be provided.

7b. SYSTEMS

The post-holder will be proficient in the use of the NHS Research Scotland (NRS) R&D database (SReDA), the Health Research Authority (HRA) Assessment Review Portal (HARP), National Institute for Research (NIHR) interactive Costing Tool (iCT), the ACCORD Sharepoint system, and be able to produce complex spreadsheets and reports from these.

Other examples of systems which will be used when undertaking the role:

eEmployee Support System (eESS)

Personal Development Recording system (TURAS/LearnPro)
Microsoft Office (Word, Excel, PowerPoint, MS Teams), Adobe Acrobat, Adobe Sign and e-mail.

Note: New systems may be introduced as the organisation and technology develops, however training will be provided.

8. ASSIGNMENT AND REVIEW OF WORK

The post holder will report to the Head of Research Governance, who will review the post-holder's work in line with NHS Lothian Personal Development Review Policy and the Knowledge and Skills Framework.

The post holder will work with minimal supervision.

As an expert in the R&D governance of commercially sponsored research in the UK, the post holder is expected to make autonomous decisions on a daily basis regarding the interpretation and application of clinical research legislation and clinical trial agreements.

The post holder will be required to determine the priorities for their role and to manage their workload, and that of their team, to achieve ambitious national targets for granting R&D permission for commercial research projects and amendments to projects taking place in NHS Lothian.

9. DECISIONS AND JUDGEMENTS

Use expert research knowledge and skills to assess study protocols, addressing issues of organisational risk, scientific validity, resource utilisation and practical feasibility.

As a national expert, uses initiative and expertise to interpret and advise on national research governance policy.

The post holder works autonomously and has the ability to organise, prioritise and exercise initiative in managing work on a day-to-day basis.

Makes decisions, often complex, on attribution of costs for commercial clinical research projects using available information and in discussion with researchers. The post holder may identify discrepancies in costing information and will be required to propose remedial action.

Decides when research costs in clinical trial agreements must be adjusted and significant sums negotiated to ensure full cost recovery is achieved for NHS departments. The outcome of such decisions may determine whether a study can go ahead or not.

Recognises significant funding trends, governance and indemnity issues and decides when to alert CSO to potential risks.

Recognising and acting upon staff performance issues that necessitate education, support, counselling or disciplinary action.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

Balancing the needs of multiple stakeholders, discussing complex legal issues with external study Sponsors and commercial research organisations, when reviewing studies and negotiating contracts on behalf of several Scottish Health Boards.

Achieving optimal financial remuneration for contract clinical research projects while avoiding protracted discussions that compromise target R&D permission times.

Maintaining oversight of governance review activity in a large and diverse portfolio of national clinical research projects, ensuring that CSO permission timelines are achieved, whilst maintaining transparent working procedures and having the knowledge and confidence to apply a policy position which can be contrary to the preconceptions of the external Sponsor/Commercial Research Organisation. This can involve withholding R&D approval in the face of intense pressure from senior researchers and other stakeholders.

Identifying specific problems with clinical trial agreements that may prevent the trial from progressing, seeking practical solutions to enable the study to go ahead e.g. outsourcing laboratory support for novel tests that cannot be undertaken locally.

11. COMMUNICATIONS AND RELATIONSHIPS

Required to communicate complex information both orally and in writing, internally to colleagues and externally to a range of audiences (local, national and government level) is central to this post, as is the ability to form functional working relationships with a wide range of individuals within NHS Scotland Board R&D offices at all levels.

The post holder is expected to communicate by formal methods including presentations to the CSO and larger groups from the clinical research community. The post holder is expected to document governance, costing and contractual decisions to researchers at all levels of seniority, commercial sponsors, other R&D management staff and CSO. Informal communication methods include one-to one meetings, telephone conversations, MS Teams meetings and written communication. The nature of the communication can be challenging and the post holder is expected to be able to communicate complex matters appropriately and to ensure that the individual receiving the communication understands the issues.

Communication is required with:

- National generic governance reviewers in NHS Lothian and in other NRS nodes (Aberdeen, Dundee, Glasgow).
- Head of Research Governance.
- Research Coordinators.
- Research Governance Officers.
- R&D Amendments Officer.
- Principal R&D Manager & R&D Contracts Manager.
- R&D Director and Depute.
- Senior staff in the Chief Scientist Office.
- NRS Industry Portfolio Manager.
- Commercial Sponsors & Contract Research Organisations.
- R&D office staff from NHS Lothian and the University of Edinburgh.
- Senior Consultants and academics engaged in research across the UK.
- Senior representatives in commercial funding and sponsoring bodies including pharmaceutical companies, charities and research councils.
- Research Nurses, Allied Health Professionals and Data Managers.
- Staff within clinical support departments (e.g. Pharmacy, Radiology and Laboratories).
- NHS Lothian Information Governance/IT Security (e.g. Information Security Project Manager).
- NRS Permissions Coordinating team and R&D staff within/out-with the UK.
- Board Service and Senior Managers (Heads of Service, Clinical Directors and Chief Nurses).

12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical Skills and Effort:

This is largely a desk based job requiring frequent use of personal computer, telephone and other office equipment.

Mental Effort:

Intense concentration required when interpreting complex protocols, legislation and contracts.

Emotional Effort:

Exposure to controversial research information can sometimes be distressing.

Frequent need to challenge, alter and overrule the work-patterns of senior researchers and external stakeholders.

Post holder regularly has to give researchers information and advice that they do not readily wish to acknowledge or accept, this requires strong persuasive skills and an ability to say no when necessary.

Clinical Research is an evolving field, which is constantly changing and developing. The post-holder will have to be able to adapt quickly to accommodate the changing demands of NHS Lothian, Health Boards, university and commercial sectors and central government.

Environmental Conditions:

Requirement to use computer/keyboard and other office equipment more or less continuously on most days. Requirement to travel to other sites within NHS Lothian when needed e.g. to provide training or attend face to face meetings with stakeholder.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

Educated to SCQF level 11 e.g. masters in a clinical or life sciences related subject or equivalent experience.

Proven experience of working in a leadership role within a healthcare research setting demonstrating 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 UK Policy Framework for Health and Social Care Research, Medicines for Human Use (Clinical Trials) Regulations, Adults with Incapacity (Scotland) Act, Data Protection Act/General Data Protection Regulation (GDPR), Governance Arrangements for Research Ethics Committees and Human Tissue Acts.

Up to date training in ICH GCP (International Conference on Harmonisation Good Clinical Practice).

Significant working knowledge of clinical research in the public sector including NHS support and funding policy.

Working knowledge of a range of research methodologies (e.g. quantitative and qualitative research).

In depth understanding of costing policies associated with conducting clinical research including the NIHR interactive costing tool (iCT).

Working knowledge of Health Research Authority model agreements.

Research management experience.

Proven interpersonal skills to work with clinical and management colleagues at all levels across a range of organisations.

Proactive, self-motivated with ability to motivate and influence others, demonstrating well developed negotiation skills, diplomacy and good judgment.

Proven experience of communicating complex information orally, in writing and through formal presentation.
Proficient in use of Microsoft Office applications.
Well-developed organisational skills to ensure competing priorities are achieved to agreed timescales.

14. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each job holder to whom the job description applies.

Job Holder's Signature:

Date:

Head of Department Signature:

Date: