



JOB DESCRIPTION

1. JOB IDENTIFICATION

Job Title: R&D Information Governance Lead

Responsible to (insert job title): Principal R&D Manager

Department(s): Academic & Clinical Office for Research & Development (ACCORD)

Directorate: Department of Public Health and Health Policy

Operating Division: Corporate

Job Reference: 059005

No of Job Holders: 1

Last Update (insert date): May 2021

2. JOB PURPOSE

Deliver Information Governance expertise and delegated Caldicott Guardian approval for clinical research in NHS Lothian, as subject matter expert for the Academic and Clinical Office for Research and Development (ACCORD).

Coordinate the R&D management approval pathway for clinical research studies that involve digital technology, transfer of participant data out with NHS Lothian and/or the use of unconsented healthcare data.

3. DIMENSIONS

The Academic & Clinical Central Office for Research & Development (ACCORD) Sponsors and hosts a large and diverse portfolio of clinical research projects totalling approximately 1000 per annum and it receives around £10,000,000 of Scottish Government funding each year.

The ACCORD team is comprised of approximately 50 people, supporting a variety of functions that include: clinical research governance, clinical research facilitation, clinical trial monitoring, research contracting and pharmacovigilance.

Client groups include NHS and University staff of all disciplines and levels (approximately 1500 researchers in Lothian) and external researchers from across the UK and beyond.

Under established Terms of Reference, the NHS Lothian Caldicott Guardian has granted delegated authority to specified post holders within R&D, to enable provision of Caldicott approval for selected clinical research studies.

Approximately 150 research related Caldicott Guardian applications are submitted to ACCORD annually and this is increasing year on year. Of these, around 50% require additional Information Governance/IT Security advice to ensure compliance with legal requirements and local policies.

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

Staffing Responsibilities:

The post holder will work across multiple clinical research sites within NHS Lothian and the University of Edinburgh (UoE) and contribute to the delivery of local and national training packages for the research community.

The post holder will provide Information Governance training for ACCORD staff, clinical researchers at all levels of seniority and their research teams.

The post holder will provide leadership and supervision to ACCORD staff who undertake information governance reviews for clinical research studies.

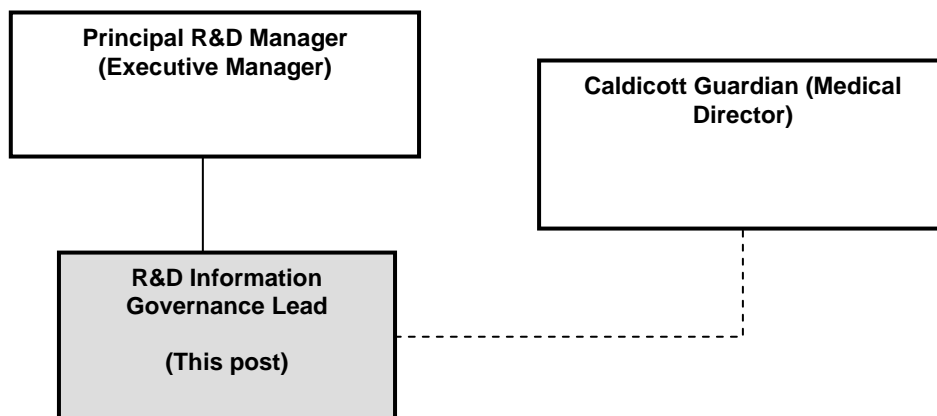
Financial Responsibilities:

The post holder will be responsible for ensuring adequate financial remuneration is included in data sharing and data processing agreements to cover NHS Lothian's costs in respect of these activities and to influence and enable investment that meets future resource needs.

4. ORGANISATIONAL POSITION

Key: Solid line = Direct Line Management

Dotted line = Regular reporting and discussion regarding delegation of authority for research applications



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:

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).

Implementing Research Governance initiatives and delivering the Local Research Governance Implementation Plan across NHS Lothian.

Implementing the NHS Lothian R&D strategy, to inform future development of policy.

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.

Ensuring Investigators and NHS Lothian are fully compliant with all legal responsibilities associated with hosting Clinical Trials, and other clinical research.

Facilitating good quality, well managed research; providing support and building systems which encourage a broad and dynamic research culture within NHS Lothian.

Facilitating the building and development of regional research networks, encouraging well-governed research collaborations and supporting state-of-the-art clinical research facilities.

Managing commercial research, negotiating appropriate contracts with commercial (and non-commercial) partners, administering research income and ensuring financial probity.

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 eligible 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.

DataLoch was co-created by the University of Edinburgh and NHS partners to act as a repository of health and social care data for the Edinburgh and South East Scotland (ESES) region with the vision to:

“Enable improvements in data-driven health and social care outcomes by delivering a world-leading data service”.

6. KEY RESULT AREAS

Information Governance & Delegated Caldicott Guardian Responsibility

1. Lead the delivery of an information governance review system for clinical research, ensuring that projects are robustly assessed to ensure compliance with Data Protection Legislation and NHS Lothian eHealth policies for the collection, transfer, sharing and storage of personal, identifiable data.
2. With delegated responsibility from the NHS Lothian Caldicott Guardian (Medical Director), lead on Caldicott Guardian assessments for clinical research projects that involve the use of mobile devices and/or unconsented patient data (including special category and sensitive data), providing expert analysis, guidance and support to research staff. Responsible for ensuring that Caldicott Principles are upheld and requests for Caldicott approval are fully justified and documented, escalating these reviews to NHS Lothian's Caldicott Guardian for further consideration if required.
3. Working with the R&D Information Security Project Manager in eHealth, review and follow up IT Security recommendations for clinical research projects where use of personal identifiable data (fully consented) is transferred out with NHS Lothian, taking into account risk and the scientific merit of the work and its value in terms of benefits to patients and the NHS.

Policy, Planning and Service Development

4. Interpret complex legislation relating to information governance and data protection, identifying the implications for clinical research and acting to minimise organisational risk by ensuring that a robust governance framework is in place to safeguard research participants' confidential information.
5. Be proactive in formulating local policy related to the above seeking input from the Principal R&D Manager as required (e.g. producing ACCORD Standard Operating Procedures (SOPs), ACCORD website guidance and NHS Lothian Generic Data Protection Impact Assessment). Plan ahead for imminent and long-term legislative changes, monitoring emerging trends in research priorities and anticipating additional resource needs arising from new research methods, regulatory requirements and increasing workload.
6. Work in close collaboration with the ACCORD Research Governance teams (NHS Lothian and University of Edinburgh), senior colleagues from eHealth, DataLoch, NHS Lothian's Research Safe Haven and NHS Research Scotland (NRS) to implement national policy in this area.

Information Resources

7. Grant R&D management approval to data studies that are undertaken through the DataLoch, ensuring that a delegated research governance review has been completed and essential project details are recorded in the national R&D database, SReDA.
8. Maintain a comprehensive inventory of Caldicott Guardian applications and IG/IT Security reviews for clinical research, tracking their progress, outcomes and the supporting evidence used to inform decision making. Monthly reports of Caldicott applications approved to be provided to the NHS Lothian Caldicott Guardian.
9. Prepare and deliver reports, presentations and briefing papers required by ACCORD, NHS Lothian Board and NHS Research Scotland (NRS) to highlight and quantify use of health records in research and inform future strategy in this area.

Research Data Sharing Agreements

10. Work in close collaboration with the Principal R&D Manager to draft, review, negotiate and finalise data sharing and processing agreements for hosted and sponsored clinical research, giving guidance as needed and seeking legal advice or providing instruction to the Central Legal Office (CLO) where the post-holder deems that this is required. The post-holder will deal with complex agreements on behalf of NHS Lothian Board. Identify and reduce any potential risks or liabilities falling to NHS Lothian under these agreements.

Quality Assurance & Performance Review

11. Set up and continuously monitor robust, streamlined internal governance systems which provide the accountability required by the appropriate legislation, Scottish Government and NHS Lothian policies. Ensure all internal and external reporting requirements are met.

12. Monitor workflow and reassess priorities as required, negotiating with stakeholders to manage urgent government deadlines, conflicting workload pressures and ambitious researcher expectations.

13. Approximately 10% of the role will be to develop and deliver training relating to data protection, information governance and Caldicott Principles to ensure that researchers understand and apply the highest standards of information governance within their clinical research, working closely with ACCORD Sponsor representatives and the wider research community to share best practice and build safeguards into study design.

14. 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.

Finance

15. The post holder will be responsible for ensuring adequate cost recovery is included in data sharing and data processing agreements to cover NHS Lothian's costs in respect of these activities and to enable financial sustainability that meets future resource needs

7a. EQUIPMENT AND MACHINERY

The following are examples of equipment which will be used when undertaking this role. PC, telephone, pager, scanner, photocopier, automated medicines storage system.

Desktop and laptop computer.

Desktop and network printer.

Document Scanner/Document Shredder/Photocopier.

Telephone/Teleconferencing Equipment.

Videoconferencing Equipment/Power Point Projector/Web cam/Digital Camera.

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

7b. SYSTEMS

The following are examples of systems which will be used when undertaking the role:

Proficient user of IT systems relating to research within NHS Scotland including the Infonetica

SReDA system for Research Management.

Regular user of MS Office Suite of software including TEAMS, SharePoint, Excel, Word, Access and Power-Point in order to communicate effectively with colleagues, establish databases and provide routine, exceptional and ad hoc reports.

TURAS system for appraisal and personal professional development.

Incident reporting systems e.g. DATIX.

eESS / SSTS HR system – electronic staff records for absence, training, holidays.

JobTrain National Recruitment System.

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 work autonomously with minimal supervision.

Formal line management reporting for the post holder will be to the Principal R&D Manager

Work is generated through research submissions and informal enquires to ACCORD.

The post holder will determine the priorities for their role and manage their workload to achieve challenging national targets for granting R&D permission.

A great deal of flexibility will be required to respond to requests made at short notice e.g. Urgent Public Health (UPH) projects that are time critical.

9. DECISIONS AND JUDGEMENTS

The post holder is required to make autonomous, case by case decisions about whether to grant delegated Caldicott approval for the use of unconsented patient data in clinical research projects and/or use of mobile devices, and when NHS Lothian Information Governance/IT Security risk assessment is required. This includes assessment of regulatory compliance, compliance with NHS Lothian and ACCORD policies and procedures, the scientific value of the study and the track record and expertise of study applicants.

When projects involve unconsented, special category data that are particularly sensitive or complex, the post holder must contribute to complex decision making regarding the risk benefit balance of approving clinical research projects where use of patient data is fully consented but IT security recommendations cannot be met in full. The post holder must recognise when it is necessary to seek external, specialist expertise to inform their decision making and to determine when it is appropriate to escalate the final decision to NHS Lothian's Caldicott Guardian.

Identifying IT security recommendations that are compulsory before a study can proceed and recognising recommendations that have already been satisfied within the project plan and reviewed by NHS Lothian R&D governance.

Occasionally the post holder will be required to apply expertise and discretion to approve projects in which incomplete implementation of IT security recommendations, is mitigated by alternative safeguards. For example consider the impact for patients when a trial offers their only remaining treatment option and/or the potential scientific value of the project is significant or the wider organisational risks associated with turning down studies e.g. reputational risk to the institution if patients cannot access trials in Lothian that are open in other Scottish/UK Health Boards, damage to important academic and commercial research collaborations (local, national and international).

The post holder will decide what requests should take priority from a large caseload of projects e.g. UPH studies that require expedited review or time limited opportunities to participate in

prestigious scientific investigations.

The post holder will review and interpret data sharing and processing agreements and decide when these need to be adjusted and re-negotiated with commercial and non-commercial partners. The outcome of such decisions may determine whether a study can go ahead or not.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

The post-holder will have to juggle a number of priorities at any one time, making sure that timelines are adhered to and accuracy is maintained. Research permission times are set nationally by the Chief Scientist Office.

The post-holder will have to tackle situations that require significant tact and diplomacy (e.g. resolving conflict between external Sponsors, commercial clients and researchers).

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 study Sponsor. This can involve withholding R&D management approval in the face of intense pressure from senior researchers and other stakeholders.

Health records research is a rapidly developing area which the Scottish Government has prioritised for growth. Decisions and judgements cannot always be directly based on precedent or prior experience and there is a high level of potential reputational risk. The post holder must be able to evaluate new requests from researchers, government, external Sponsors and industry. This will involve negotiating compromises and new approaches if necessary to make clear, justifiable and prompt decisions which benefit NHS patients and research partners.

Engaging effectively with stakeholders, so that they understand why and how specialist health information should be used in research without compromising confidentiality and in compliance with data protection legislation and NHS Lothian policies and procedures.

11. COMMUNICATIONS AND RELATIONSHIPS

Communication is a key element of the role. The post holder is required to have excellent communication, negotiation and inter-personal skills to develop and maintain telephone, e-mail and face-to-face communication with a wide range of internal and external contacts. The communication is to articulate information related to data protection, information governance and the Caldicott Principles. The nature and format will vary from formal reports or specifications that form part of a contractual document set, to presenting concepts to large stakeholder audiences or facilitating detailed discussions with researchers and study Sponsors.

Act as subject matter expert on the use of healthcare records for research.

Manage conflicting views within and about the service and undertake sensitive, sometimes difficult, conversations with discretion.

The post holder is often required to deal with controversial or sensitive research information which can be distressing (e.g. research related to areas that differ to the post holder's own beliefs).

Develop and manage effective and credible relationships with a wide range of stakeholders, to maintain integrity, influence outcomes, manage expectations and mediate where expert opinion may differ.

Anticipate customer and/or stakeholder concerns and reactions, pre-empting them where possible by anticipating and addressing them.

Key Relationships:

ACCORD Senior Managers and ACCORD Research Governance Teams.
Medical Director, Caldicott Guardian.
Information Governance Manager, NHS Lothian.
Data Protection Officers (NHS Lothian and University of Edinburgh).
eHealth Project Managers, in particular the R&D Information Security Project Manager.
DataLoch Information Governance Manager.
DataLoch Information Governance Facilitator.
Project teams and researchers.
NHS stakeholders.
Relevant Governance Bodies.
Scottish Government and other safe haven services in Scotland.

Internal

Frequent contact with project sponsors and R&D governance team to ensure appropriate user input and report progress.
Attend meetings and deliver training (e.g. on data protection and Caldicott Principles) to researchers and ACCORD colleagues as appropriate. Such events can involve presentations to large groups of people, e.g. 20-40 individuals, occasionally up to 100.
Meetings with line manager to report on progress and discuss personal development.
Frequent contact with other staff within NHS Lothian, Medical Director/Caldicott Guardian, eHealth Project Managers, Information Security Project Manager, other senior managers in NHS Lothian, NHS and University based researchers.

External

Managers, academics and other senior staff in NHS in meetings, occasional presentations, or on project boards as required to report on progress, promote the skills and services of the service, ensure user feedback on current projects and services and identify opportunities for new developments.
Regular face-to-face or other contact with multidisciplinary clinicians from all specialties, and information/record staff in primary and secondary care, and social work on the development and use of corporate databases.
Customers in universities, other NHS and non-NHS Organisations e.g. SHARE, commercial organisations, Contact with similar services in other organisations in Scotland and across the rest of the UK to ensure consistency of approach.

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

Physical:

Keyboard skills requiring high degree of speed and accuracy.

Mental:

Intense concentration required when interpreting complex protocols, legislation and contracts.
Frequent need to reprioritise workload, review and quickly understand large amounts of new and complicated information including draft contracts, legal advice provided by the Central Legal Office, research policies and legislation.

Emotional:

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

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.

Environmental:

Requirement to use computer/keyboard and other office equipment more or less continuously on most days. Frequent requirement to travel within the Board area and throughout Scotland and the rest of United Kingdom.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB**Qualifications & Training**

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

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

Experience

Proven experience of working in a leadership role within a healthcare research setting demonstrating ability to work effectively as part of a team.

Advanced working knowledge of information governance within the healthcare research setting: Caldicott Principles, the Common Law Duty of Confidentiality and Data Protection Legislation.

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, 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.

Significant working knowledge of clinical research in the public sector including a range of research methodologies (e.g. quantitative and qualitative research).

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.

Excellent time management skills with ability to plan and work to agreed timescales and to multi-task effectively under pressure, maintaining high quality work.

Experience in delivering formal training.

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: