JOB DESCRIPTION

1. JOB IDENTIFICATION

Job Title:	Deputy Director Research and Development (R&D)
Responsible to:	Director Research & Innovation (R&I) – NHS Lothian
Department(s):	Research and Development - ACCORD
	(Academic and Clinical Central Office for Research and Development)
Directorate:	Corporate
Operating Division:	NHS Lothian
No of Job Holders:	1

2. JOB PURPOSE

The post holder will have managerial responsibility for the ACCORD office (Academic and Clinical Central Office for Research and Development), a Joint Research Office, comprising R&D management staff from NHS Lothian and the University of Edinburgh (UoE), providing management and oversight of R&D within NHS Lothian and in collaboration with the UoE College of Medicine and Veterinary Medicine (CMVM), other relevant Higher Education Institutions (HEIs) and Edinburgh BioQuarter.

To provide expert leadership, management, operational research delivery and policy development to NHS Lothian's R&D function. The post holder will ensure that systems and processes are in place to deliver high quality clinical research that meets stringent regulatory requirements. Responsible for the NHS Lothian / UoE Statutory Good Clinical Practice (GCP) Systems inspection on behalf of both organisations.

To facilitate the effective use of R&D infrastructure funding and delivery of research governance in accord with national standards and relevant legislation.

To represent NHS Lothian in relation to R&D including regular meetings with the Chief Scientist's Office (CSO) and representation on a range of national groups across Scotland and the UK.

3. DIMENSIONS

NHS Lothian provides area wide population health, primary care and specialist services to a population of around 900,000 in Lothian within an increasingly integrated health and social care system. NHS Lothian provides tertiary specialist services to approximately 1.3 million people in the East of Scotland and hosts several national services. NHS Lothian employs around 28,000 staff of whom more than 700 are consultants. The majority of these are NHS consultants but around 100 are University of Edinburgh employed clinical academics who have honorary consultant contracts

with NHS Lothian.

The majority of these clinical academic staff, and many NHS consultants, undertake extensive basic, clinical and translational research & development programmes, which involve patients treated in NHS Lothian hospitals, community services and in primary care. An increasing number of staff from all professions participate in research, particularly in research related to the delivery of health services and improved health outcomes. Our ambition is to ensure that R&D is at the heart of our work to address all determinants of health, including social determinants, and to transform the health system for our population.

The NHS and University of Edinburgh R&D office is integrated as a single Academic and Clinical Central Office for Research and Development (ACCORD). The office is responsible for reviewing grant applications and pre-award administration; risk assessment; governance and monitoring of research including clinical trials; financial administration; audit of outcomes; and the identification, protection and exploitation of intellectual property.

The post holder will be responsible for delivery of NHS Lothian's Research and Development (R&D) strategy and the provision of support to all NHS and academic investigators within the Lothian area wishing to undertake R&D activity. NHS Lothian has a strong track record in delivering clinical trials ranging from phase 1 "first in man" studies to large pragmatic multicentre phase 3 trials. As such, there is close working with Edinburgh Clinical Trials Unit (ECTU), Edinburgh's MHRA Accredited Clinical Research Facilities (CRFs) and other University facilities involved in the delivery of clinical research e.g. Edinburgh Imaging.

Major external partners include: University of Edinburgh (in particular College of Medicine and Veterinary Medicine, but including the wider University), Queen Margaret University, Napier University, Heriot-Watt University, Strathclyde University, NHS Research Scotland (NRS) Networks and Specialty Groups, InnoScot Health (Technology Transfer Office).

ACCORD's client group comprises NHS staff (all disciplines and levels from across the UK), academics, students, commercial and third sector stakeholders. Size of client group approximately 1500 researchers.

Number of research projects across Lothian (approx.) 1200: number of new projects per year (approx.) 450; with a further 170 commercial projects, income from which is over £3,000,000 per annum for Lothian. The R&D portfolio is a mixture of Sponsored, hosted (non-commercial academic) and commercial projects.

The number of commercial research projects is set to increase by 25% over the duration of the Voluntary Scheme for Branded Medicine Pricing, Access and Growth (VPAG) investment. VPAG is a five-year initiative to support the expansion and enhancement of UK capacity to deliver commercial clinical trials. The agreement between the UK government and Association of the British Pharmaceutical Industry (ABPI), involves an investment across the four UK nations, which includes the establishment of around 20 Commercial Research Delivery Centres (CRDCs), including that which was recently developed at the Western General Hospital (WGH) in NHS Lothian.

Financial Responsibilities:

In conjunction with the R&I Director, the post holder is responsible for using the budget provided via the Chief Scientist Office (CSO), Scottish Government to meet national objectives and targets set by CSO. The postholder manages all elements of NHS Lothian's CSO budget which is comprised of allocations for Generic Infrastructure, Researcher Support, Service Support, NRS Mental Health Network, NRS Safe Haven, NRS Biorepository, NRS Specialty Groups, NRS Fellowships, R&D Management and Patient and Public Involvement (PPI).

Management and disbursement of the separate, five-year funding investment (currently £6.7M) from the Voluntary scheme for branded medicines Pricing, Access and Growth (VPAG).

The post holder has authority to sign off financial contracts on behalf of the organisation up to £100,000 and is the Service Director signatory for Recruitment Authorisation Forms for clinical research staff in NHS Lothian.

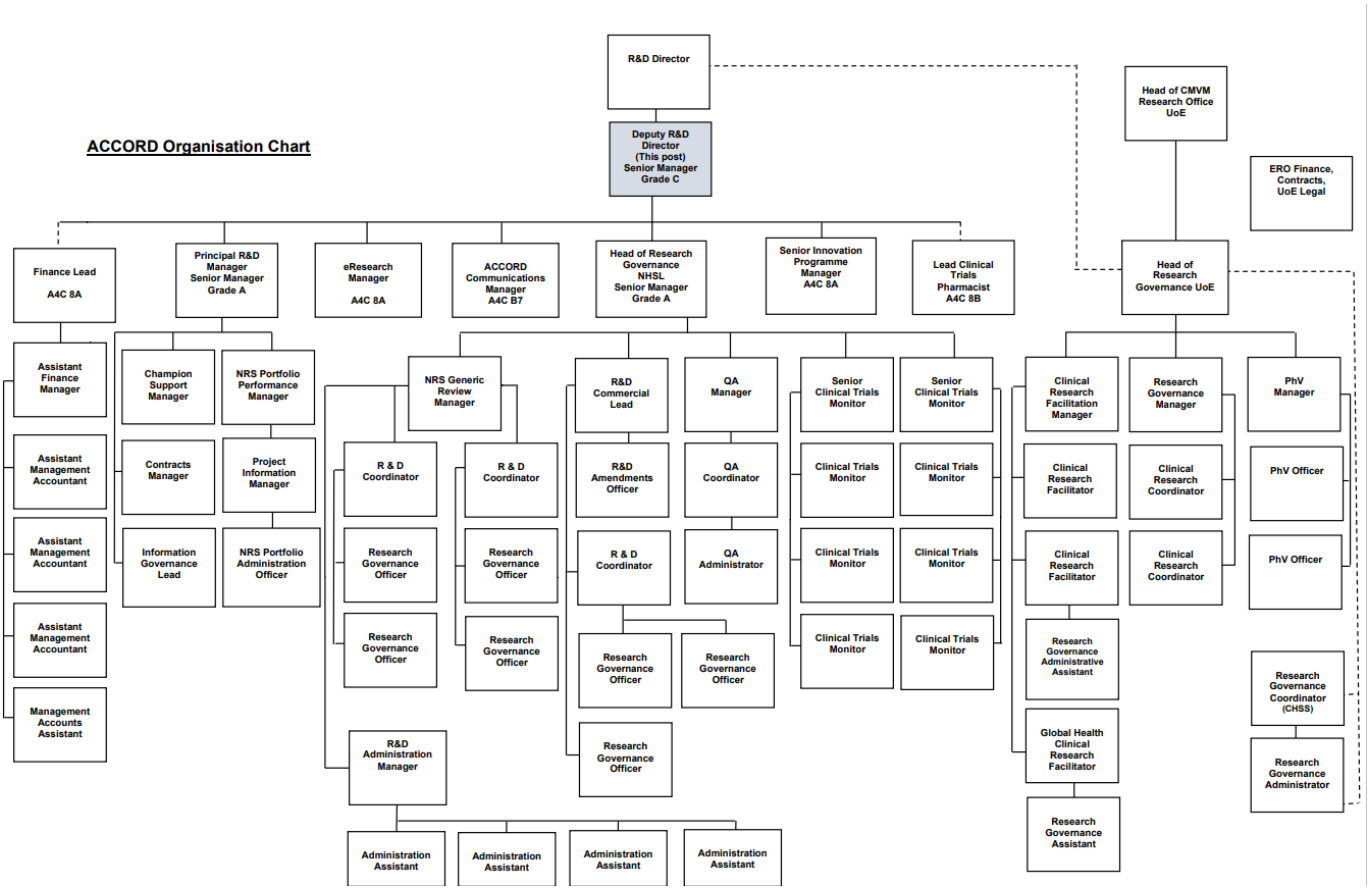
Staffing Responsibilities:

The ACCORD office comprises 44 WTE NHS staff and a further 10 WTE UoE staff.

The post holder is the senior operational manager for ACCORD and has direct line management responsibility for 5 WTE members of NHS staff: 2 x Senior Manager Grade A, 2 x Agenda for Change Band 8A and 1 x Agenda for Change Band 7.

The post holder also closely supervises 1 x Agenda for Change Band 8A (R&D Finance Manager) and 1 x Agenda for Change Band 8B (Lead Clinical Trials Pharmacist).

4. ORGANISATIONAL POSITION



5. ROLE OF DEPARTMENT

NHS Lothian is a research active NHS Board with close associations with a large medical school (University of Edinburgh, College of Medicine and Veterinary Medicine (CMVM)), other colleges within University of Edinburgh and the other Higher Education Institutions serving the NHS and partners. The ACCORD joint R&D office is a collaboration between NHS Lothian and the University of Edinburgh, according to a framework agreement setting out the responsibilities of each partner in the support of clinical research. The ACCORD R&D Office has corporate responsibility for the management of Research and Development throughout NHS Lothian. Almost all studies led through ACCORD are co-sponsored by the UoE and NHS Lothian.

R&D is a fundamental component of Healthcare Governance at all levels. The ACCORD Office has responsibility for implementation of all aspects of research governance as outlined in the UK Policy Framework for Health and Social Care Research or as required by legislation through the Medicines & Healthcare products Regulatory Authority (MHRA) in relation to clinical drug, device, or other regulated trials. This includes assurance of Good Clinical Practice (GCP), pharmacovigilance, project monitoring and audit, dissemination of research findings and recommendations for progress from research into practice. The remit of ACCORD is to provide a 'one-stop shop' for clinical researchers to maximise research quality and opportunity for all groups of professional staff in collaboration with academic partners, while minimizing corporate risk and focussing on future service needs. This includes developing standard operating procedures (SOPs) for research management and implementation of R&D policies and procedures on behalf of the Board, monitoring research activity and reporting to appropriate bodies.

The ACCORD R&D Office provides the following services:

Bidding for, managing and reporting on the R&D infrastructure funding received by NHS Lothian from the Scottish Executive Health Department via the Chief Scientists office (CSO). This is allocated annually via Service Level Agreements (currently standing at over £12 million).

Implementing Research Governance initiatives and delivering local or national guidance and/or legislation in relation to research governance (for example as set out by the Health Research Authority (HRA), MHRA, or the Chief Scientists Office).

Implementing the NHS Lothian R&D strategy.

Facilitating high quality, well managed research; providing support and building systems that 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.

Working with the University of Edinburgh College of Medicine and Veterinary Medicine to ensure that a single system of working across Lothian enables the College to fulfil its responsibilities as outlined in law and in Research Governance.

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

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.

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

Identifying, managing and commercialising NHS Lothian Intellectual Property (IP), in collaboration with the relevant national bodies.

Ensuring that NHS Lothian takes full advantage of the development and the commercialisation of IP in line with NHS Scotland and Scottish Government requirements.

Developing and sustaining the NHS Research Safe Haven function, and Data Loch.

Overseeing the management and governance of the NHS Lothian Biorepository.

Supporting effective patient and public engagement and collaboration in R&D.

Working with all HEIs in Lothian and beyond to ensure greatest collaboration in quality research with minimum duplication of effort.

To support the communication, dissemination and adoption of learning from funded R&D activity.

6. KEY RESULT AREAS

Strategic Direction

1. In conjunction with the R&I Director, the Deputy Director is responsible for driving the development, revision and implementation of the NHS Lothian R&D Strategy that informs clinical practice and helps ensure a sound evidence base, to address national and local priorities. Leading the ACCORD Senior Management Team (SMT) to anticipate and shape an annual operational plan, aligned to NHS Lothian's R&D Strategic Plan and NHS Research Scotland (NRS) goals, including key outcomes and milestones.

2. Responsible for delivery of the R&D strategy, ensuring that it is supported by infrastructure and operational arrangements to sustain research at the highest level and that research is aligned with the configuration of clinical and corporate services.

3. Responsible for planning and developing new R&D programmes tailored to meet NHS Lothian's priorities and needs e.g. clinical trials of Advanced Therapies, including production of business cases to support these initiatives.

4. To undertake interaction with the University of Edinburgh and other HEIs, including Queen Margaret, Napier, Heriot-Watt and Strathclyde Universities, in relation to collaborative R&D programmes, funding and appropriate research governance in order to pool resources, optimise scientific outputs and ensure delivery of world class clinical research that complies with stringent legislation and benefits patients.

5. To nurture and implement strategic partnerships with academia and industry e.g. Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland (CATALYST) to increase the number of commercial research studies placed in Scotland and support the national objective of establishing the UK as a global leader in clinical trials and medical research.

6. Create formal structures for communication and networking to promote and facilitate multidisciplinary working between professions, departments, healthcare sectors and institutions to enhance researchers' ability to tackle complex clinical problems that require multiple perspectives.

7. Responsible for planning and delivering public-facing communications and engagement events to showcase Lothian led research as well as promoting NHS Lothian as an outstanding location to deliver research, to both internal and external audiences e.g. via ACCORD Annual Brochure, biennial NHS Lothian R&D Conference, ACCORD website, to research funders, academic and industry representatives, the public, NHS R&D Forum colleagues and other partner organisations.

Clinical Research Governance

8. Responsible for implementing all aspects of Research Governance across NHS Lothian as outlined in the UK Policy Framework for Health and Social Care Research, ICH Good Clinical Practice Guidelines and the UK Clinical Trial Regulations, acting as the escalation point for research-related incidents and complex governance issues.

9. Interpret UK legislation and develop local policies and procedures which will ensure compliance with the national laws and guidance laid down for the conduct of clinical research within the NHS to ensure implementation of policy decisions in relation to R&D across NHS Lothian.

10. Responsible for providing effective Quality Assurance across the research portfolio with robust monitoring systems and management of pharmacovigilance reporting, ensuring patient safety is maintained. Liaise with clinical trial staff on patient treatment and randomization into specific studies, ensuring the health and well-being of the patients, acting to halt studies if needed.

11. To undertake investigations into cases of research misconduct or research non-compliance, working collaboratively with members of the ACCORD Senior Management Team and partner organisations as required. This will require communication of highly complex, sensitive and/or contentious information, maintaining confidentiality and being sensitive to organisational risks and ensuring that investigations follow all applicable institutional policies.

12. Responsible for ensuring compliance with Good Clinical Practice throughout the research portfolio, with particular emphasis on activity for which NHS Lothian and UoE are co-Sponsors and on Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (CIMD) where compliance is mandatory and subject to regulatory inspection, resulting in no major findings from any MHRA inspection.

R&D Management

13. Responsible for the governance oversight of all research studies and clinical trials being delivered across the Board, relating to adequate compliance with all relevant research regulations ensuring safety of participants and protecting the integrity of the data. This will require use of efficient and effective systems and processes e.g. source data verification, vendor assessment and strong collaboration and coordination with the Board's support departments (imaging, pathology, pharmacy, labs, medical physics and information governance) as well as other corporate services (such as the Central Legal Office) and our research partners.

14. Manage delivery of R&D services in relation to Key Performance Indicators (KPIs), making service improvements across all teams where needed to be responsive to the needs of investigators, CSO and to meet UK wide performance targets. This will involve analysis of the full research portfolio, timelines for the turnaround of studies and contracts, staff workloads and collaboration with partners to ensure effective delivery against performance metrics for all hosted and co-sponsored studies.

15. Lead on developing and refining data management processes to improve reporting of research data that supports strategic initiatives to improve research performance. Analyse complex facts and situations, providing an interpretation and comparison of options to the R&I Director and Senior Management Team e.g. assess fragmented and incomplete data sources (multiple platforms, inconsistent definitions) for key research metrics (recruitment figures, study approval / completion times, Equality, Diversity and Inclusion indicators, research income etc) and identify potential systems solutions that enable comprehensive reporting.

16. To collate, analyse and interpret complex benchmarking data to inform decision making with respect to service delivery and design, including monitoring performance against set national targets for the new Commercial Research Delivery Centres (CRDCs).

17. To provide oversight for the Clinical Research Facilities (CRFs), in collaboration with the CRF Directors, maintaining Accreditation with the Medicines and Healthcare products Regulatory Agency (MHRA) and developing an aligned Commercial Research Delivery Centre (CRDC).

18. To provide oversight for NHS Lothian Biorepository and tissue research, working with the Biorepository leads. Developing collaborations between Biorepositories, DataLoch and other key areas to enable research and Innovation within NHS Lothian and the wider NHS Research Scotland (NRS) Network.

Staff Management

19. Responsible for workforce planning within ACCORD including recruitment, personal and professional development, performance management, and employee relations including grievance procedures. Direct line management responsibility for senior managers, ensuring development of specialist skills and knowledge to deliver objectives.

20. Facilitate and participate in the management, training and appraisal of multidisciplinary NRS Fellows and Clinicians, including biannual training days and annual review of progress.

Financial Management

21. Maintain robust financial management of the R&D budget and be instrumental in increasing the funding through external initiatives and sound business planning e.g. applications for new monies through CSO and industry partnership initiatives (Moderna, AstraZeneca). In conjunction with the R&I Director, implement proposals and policies for new investment opportunities, including those arising from commercial research and intellectual property e.g. the Practice Embedded Research Unit (PERU) to advance research in Primary Care.

22. Apply and manage Lothian's annual allocation of R&D funding from the CSO (currently over £12M) according to agreed priorities, governance and compliance requirements; and invest annual income as generated from commercial trials, currently around £3M per annum. In conjunction with the R&I Director, to sign off contracts with commercial funders and academic partners on behalf of the organisation (up to £100,000) and allocate research funding to raise the quality of research and profile of NHS Lothian as a centre of excellence for clinical research.

23. Actively manage the separate, five-year funding investment (currently £6.7M) from the Voluntary scheme for branded medicines Pricing, Access and Growth (VPAG), ensuring timely disbursement of funds for staff, facilities and equipment in order that the monies are utilised effectively to increase commercial trial delivery and research opportunities for patients. Specifically, oversee the development of the new Commercial Research Delivery Centre (CRDC), new aseptic pharmacy module and upgrades to ophthalmology research capability.

24. Liaise with corporate management accounting to ensure consistent practice and compliance with NHS Scotland's Standing Financial Instructions in R&D funding and support; and fulfil CSO research expenditure reporting requirements.

25. Liaise and negotiate with key partners such as the UoE's College of Medicine and Veterinary Medicine (CMVM), in relation to financial commitments for staff and facilities required to deliver R&D within NHS Lothian, including Edinburgh Clinical Trials Unit (ECTU), Edinburgh Imaging, DataLoch and the Health Technology Accelerator Facility (HTAF).

26. Approve research grants on behalf of NHS Lothian as Board Sponsor representative and support strategic bids from a research governance perspective e.g. UK Dementia Trials Network Centre.

Education, Training and Professional Development

27. Work in close collaboration with the CRF's Education Programme Manager to consolidate new training initiatives that prepare the clinical research community for regulatory changes and developments to transform the delivery of clinical trials, ensuring a high level of awareness of research governance issues across NHS Lothian including researchers' responsibilities, contractual and training needs, funding, sponsorship and regulatory requirements. e.g. Associate Principal Investigator (PI) Scheme, Principal Investigator Pipeline Programme, new UK Clinical Trials Regulations.

Equality, Diversity and Inclusion

28. Promote and enable equality, diversity, and inclusion (EDI) across all aspects of clinical research, delivering Patient Public Involvement (PPI) services that engage patient and community groups, to identify and address barriers to participation. Monitor and report on EDI metrics and implement strategies for continuous improvement.

29. Develop and implement activities to increase awareness amongst patients and staff that clinical research is something that NHS Lothian does as a normal part of delivering care. Work directly with researchers and patient groups to increase opportunities for patients to learn about and access studies of relevance to them.

30. 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.

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 (PC) daily (desktop computer and/or laptop computer).

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

Regular use of conferencing equipment, audio and visual equipment and projectors e.g. Microsoft Teams.

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:

The post-holder will be proficient in the use of the Scottish R&D database (SReDA) and the ACCORD Sharepoint system and be familiar with the HRA Assessment Review Portal (HARP), the National Institute for Research (NIHR) interactive Costing Tool (iCT) and the NIHR Sponsor Engagement Tool (SET).

Other examples of systems that will be used daily, in addition to the above, are:

Microsoft PowerBI data visualisation software for monitoring research activity.

Dashboards for performance monitoring e.g. eEmployee Support System (eESS), Scottish Standard Time System (SSTS).

Personal Development and Mandatory Training Recording system (TURAS).

Microsoft Office (Word, Excel, PowerPoint, MS Teams), Adobe Acrobat, Adobe Sign, DocuSign and e-mail.

Intranet and internet.

DATIX for risk and complaints management.

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 is responsible to the R&I Director and is fully accountable for leading and driving progress within their established area of responsibility.

The post holder will participate in annual review and appraisal with objectives set by the R&I Director.

9. DECISIONS AND JUDGEMENTS

Manage complex regulatory issues for research studies making decisions based upon evidence about research compliance and risks, using expert knowledge in relation to the research regulatory requirements and environment e.g. determine whether a study should be undertaken in an MHRA accredited environment, reviewed by an expert committee, subject to a more intensive monitoring regime or licensing system for the investigational medicinal product under study.

Implement complex cost allocations to departments and services that contribute to improvements in the quality and nature of research activity. Allocations are calculated according to factors such as the research portfolio supported in the specialty, including the phase and intensity of the research design e.g. first-in man, the number of studies supported, any excess treatment costs incurred by the department and any pump priming investment that is required to deliver a new research programme e.g. CAR-T therapy.

Provide expert scientific and managerial input to the Research Management Committee (RMC), identifying issues of capacity, safety and compliance and making final decisions to approve, suspend or withdraw projects based on these factors.

Provide management approval on behalf of NHS Lothian for all new research activity and amendments of on-going projects making decisions based on institutional capability, capacity, compliance and financial

viability.

Make complex judgements based on expert and wide-ranging knowledge and interpretation of specific situations e.g. resolving issues relating to the treatment of patients enrolled on clinical trials which may include providing specialist advice on adverse event reporting or closing trials in emergencies.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

The post-holder will:

Adapt to a constantly and rapidly changing environment at local and national levels and influenced by changing national policies and regulations that often require urgent attention.

Be the key point of contact for complaints, escalations, issues and concerns in relation to the research governance and approvals processes, including in relation to research contracts and agreements.

Manage complex conflicting views with investigators, our partners and third parties and be required to negotiate and influence to overcome significant barriers to resolving matters of concern e.g. research misconduct or non-compliance.

Manage time effectively to meet competing demands, ensuring that work is prioritised and that outcomes are delivered timeously.

Ensure high-quality research receives a high profile and increase funding of research support in NHS Lothian.

11. COMMUNICATIONS AND RELATIONSHIPS

The post holder is expected to communicate effectively, formally, and informally with a wide range of individuals both internally and externally and will be required to develop effective and efficient systems of communication with relevant Executive Leads. The post holder is expected to analyse and convey complex and potentially contentious data and information in an understandable and professional manner. Additionally, the post holder must be able to balance views of different professionals to build consensus and progress areas of responsibility.

Internal communications:

Frequent and regular communication with R&I Director – day to day engagement about R&D strategy, service delivery, staffing, funding, CSO/NRS activity & expenditure reports etc.

ACCORD Senior Management Team – daily communication on operational matters e.g. staffing, workload & performance, specific study queries, research governance issues.

ACCORD Communication Manager – day to day engagement about essential notifications to the local & national research community, publicising scientific highlights, funding opportunities, reporting deadlines etc.

Executive Directors and NHS Board, Head of College of Medicine and Veterinary Medicine (CMVM) – ad hoc meetings and communications about strategic research priorities, infrastructure, capacity, funding, training and high-profile projects of scientific importance. Regular reporting through CMVM Clinical Trials Oversight Group (CTOG), NHS Lothian Healthcare Governance Committee and Lothian Research Committee.

Senior academics, clinical and laboratory researchers – day to day queries, meetings and requests for

information about financial support and protected time for research, funding applications, research delivery challenges etc.

External communications:

University of Edinburgh (UoE) and other HEI research partners – monthly meetings with the Head of CMVM Research & Innovation Operations to discuss strategic and operational matters relating to the Joint Research Office (ACCORD). Ad hoc meetings with other HEI partners about research collaboration, funding initiatives, Sponsorship terms, hosted research studies etc.

Scottish Government /Chief Scientist Office – scheduled meetings (minimum of 1 per month), and day to day communications about research activity, research funding, grant applications, major funding programmes, strategic investments, partnerships with industry, developments in legislation, Scottish / UK research delivery metrics etc.

R&I Directors and Senior Managers of other NHS Boards, Trusts and Hospitals throughout UK - scheduled meetings (minimum of 1 per month), and day to day communications about research activity, research funding, grant applications, major funding programmes, strategic investments, partnerships with industry, developments in legislation, Scottish / UK research delivery metrics etc.

InnoScot Health Inc and Edinburgh Research and Innovation – regular ad hoc engagement about projects involving exploitation of intellectual property, non-disclosure agreements, patents etc.

Commercial Research Organisations (CROs) – day to day engagement to progress Confidential Disclosure Agreements (CDAs), study feasibility requests and to sign off clinical trial agreements and contracts.

Commercial Sponsors – ad hoc meetings and communications to discuss commercial trial pipelines, NHS Lothian's research capability, strategic partnerships between industry sponsors and NRS Health Boards.

Association of Medical Research Charities – ad hoc meetings to discuss issues such as shared funding opportunities and models for research staff / infrastructure e.g. Cystic Fibrosis Accelerator Platform (CTAP), Alzheimer's Society / UK Dementia Trials Network.

UKRD Leadership Group – regular Teams meetings to discuss issues of national importance across the clinical research delivery system in the UK e.g. new legislation, portfolio management systems, strategic objectives, delivery metrics, funding & annual UKRD Summit.

UK Commercial Research Delivery Centre (CRDC) Network – as for UKRD Leadership Group.

Relationships:

Excellent communicator (oral, written and formal presentation) who can interpret complex legislation and impart information to a wide variety of stakeholders with different levels of understanding. Presentations are delivered to groups ranging in size from less than 10 (frequent) up to several hundred people at national conferences (occasionally).

Participate in senior and Executive level meetings, providing reliable input and identifying issues that must be taken forward.

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

Physical

Frequent, prolonged periods of VDU use when using email, interpreting research activity metrics, budgets, writing reports, reading complex protocols, grant applications and contracts.

Advanced keyboard skills for data entry and analysis and for operating a variety of research databases.

Mental

Frequent demanding meetings with CSO and NHS Research Scotland representatives, with requirement to be robustly prepared, to process information swiftly and to challenge unrealistic expectations if needed. These meetings occur at least once a month, often more frequently and at short notice.

Periods of concentration required over lengthy periods (several hours at a time) when interpreting research activity metrics, budgets, complex protocols, grant applications and contracts.

Frequent (unscheduled, daily) interruptions to deal with service issues, requiring post holder to change focus to deal with different tasks at short notice e.g. unexpected capacity or governance issue that threatens the viability of an important clinical trial.

Managing multiple actions and projects that require agile organisational skills and the mental ability to manage competing priorities within an unpredictable work pattern.

Responding to queries & complaints and communicating complex & sensitive issues with multidisciplinary research teams that require tact, diplomacy, assertiveness and negotiating skills.

Regular requirement to work to tight deadlines to meet organisational project targets or urgent requests for information from CSO.

Emotional

The post is varied and busy and the workload must be prioritised to ensure effective service delivery. The post holder's priorities won't always align with those of others, potentially leading to disagreement and conflict.

There is an occasional requirement to confront research staff, including senior academics, with issues they do not agree with and the need to overrule them e.g. regulatory compliance matters.

Occasional need to challenge medical or executive opinions in relation to essential support for research studies, including expedited approval of Urgent Public Health (UPH) studies.

Accommodating and responding to personal dynamics across a range of teams and situations and when supporting staff to change priorities or aspects of work practice.

Very occasional exposure to distressing or emotional circumstances associated with clinical trials that offer the only remaining treatment option for a condition e.g. gene therapy studies. Discussed and coordinated with the clinical care / research team.

Balancing the priorities and needs of internal and external stakeholders can be time consuming and stressful.

Dealing with conflict, criticism and complaints about R&D staff and services.

Environmental:

Frequent and prolonged use of VDU.

Travel to sites across Lothian, including relevant Higher Education Institutes (HEIs), approximately twice monthly and other NHS organisations across Scotland, approximately 6 times per year.

Occasional requirement to attend meetings and conferences elsewhere in the UK (1-2 times per year).

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

Essential:

Educated at degree and postgraduate level (master's degree or PhD) in clinical or life sciences subjects with evidence of continual professional development in clinical research.

Detailed knowledge of the UK Policy Framework for Health and Social Care Research, Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, Data Protection (UK GDPR) and Freedom of Information legislation, Human Tissue Acts and legislation relating to consent.

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

Thorough understanding and experience of service provision in the NHS, together with senior operational and line management experience.

Expert working knowledge of managing Research and Development in the NHS, with leadership experience of undergoing regulatory inspection of Sponsor systems by the Medicines and Healthcare products Regulatory Agency (MHRA).

Comprehensive and up to date knowledge of the strategy, policy and delivery systems for the Chief Scientist Office (CSO), NHS Research Scotland (NRS), Department of Health and Social Care (DHSC) and the National Institute for Health and Care Research (NIHR).

Experience of applying AcoRD guidance (Attributing the costs of health and social care Research & Development) and the mechanisms for recovering Excess Treatment Costs.

Strong leadership qualities and proven ability to work effectively as part of a team, but also self-motivated and able to work independently when necessary.

Advanced keyboard and Microsoft Office skills for presenting data/reports on a regular basis.

Preferred knowledge, training and experience

Industrial experience in healthcare R&D.

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:
(I confirm that the Job Description accurately reflects the duties and responsibilities of the postholder and does not impact upon any other postholders role)	