#### **JOB DESCRIPTION**

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| JOB IDENTIFICATION |
| Job Title: **Clinical Trials Monitor**Responsible to: Senior Clinical Trials MonitorDepartment(s): Research and Development, ACCORD\* The Academic and Clinical Central Office for Research and Development (ACCORD) is composed of NHS Lothian employees together with research management staff from the University of Edinburgh College of Medicine and Veterinary Medicine and Edinburgh Research and Innovation. These staff are currently co-located within the Queen’s Medical Research Institute and work towards a single joint system for clinical research management. Scottish Health Innovations Ltd and Medical Research Council research regulatory staff are also co-located.Directorate: Medical Director’s TeamOperating Division: CorporateJob Reference: 166394No of Job Holders: 3Effective Date: February 2008Last Update: March 2015 |

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| 2. JOB PURPOSE |
| * Work within the ACCORD monitoring programme with monitoring systems to ensure research carried out in Edinburgh is in accordance with NHS and University of Edinburgh policies, SOP, legal and regulatory requirements.
* Provide expert advice to researchers and ACCORD staff on complex research legislation to ensure that ACCORD, NHS Lothian and the University of Edinburgh researchers fulfil the legal obligations in clinical trials.
* Maintain specialist knowledge of research legislation and contribute to developing guidance to ensure compliance with the relevant legislation for all clinical research.
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| **3. DIMENSIONS** |
| * Client groups including NHS and University staff of all disciplines and levels (approximately 1500 researchers);
* Management of a monitoring programme for over 60 clinical trials of investigational medicinal products (CTIMPs) from start-up to final closure;
* Expert advice provided to a client based of over 250 clinical research professionals;
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| 4. ORGANISATIONAL POSITION |
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| **Head of Research Governance****Clinical Trial Monitor****This post****Senior Clinical Trial** **Monitor** **Deputy R&D Director** |

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| 5. ROLE OF DEPARTMENT |
| ACCORD has corporate responsibility for the management of Research and Development throughout NHS Lothian, and the University of Edinburgh, College of Medicine and Veterinary Medicine. This function is conducted on behalf of the Lothian R&D Consortium and provides the following services:* Facilitating good quality, well managed research; providing support and building systems which encourage a broad and dynamic research culture within NHS Lothian and the College of Medicine and Veterinary Medicine.
* Implementing the NHS Lothian and College R&D strategies and providing input to the Consortium to inform future development of policies.
* Implementing Research Governance initiatives and delivering the Local Research Governance Implementation Plan across NHS Lothian and the College of Medicine and Veterinary Medicine.
* Ensuring Investigators, College of Medicine and Veterinary Medicine and NHS Lothian are fully compliant with all legal responsibilities associated with hosting Clinical Trials, and other clinical research.
* Facilitating the building and development of regional research networks, encouraging well-governed research collaborations and supporting state-of-the-art clinical research facilities.
* Bidding for, managing and reporting on the R&D infrastructure funding received by NHS Lothian from the Scottish Executive Health Department (currently standing at £10,320,000).
* Managing commercial research, negotiating appropriate agreements with commercial (and non-commercial) partners, administering research income and ensuring financial probity.
* Identifying, managing and commercialising appropriate Intellectual Property, in collaboration with Scottish Health Innovations Ltd and Edinburgh Research and Innovation.
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| 6. KEY RESULT AREAS |
| **Professional**Practice at all times in compliance with:* The principles of ICH GCP
* The Medicines for Human Use (Clinical Trials) Regulations 2004 and all amendments
* Research Governance Framework for Health and Community Care
* Adults with Incapacity (Scotland) Act
* Human Tissue Act
* Data Protection Act
* NHS Lothian policies and procedures

**Clinical Trial Monitoring*** Contribute to the ACCORD monitoring programme, working with monitoring systems to ensure research carried out in Edinburgh is in accordance with NHS and University of Edinburgh policies, SOP, legal and regulatory requirements. Be accountable for monitoring within departments involved in clinical trials.
* Conduct and report monitoring visits, as assigned by the Senior Clinical Trials Monitor. Ensure all monitoring visits and findings are followed up to completion.
* Verify the trial data against the patient medical notes to ensure validity and quality. Verify informed consent of patients and that consent was taken in accordance with the relevant regulations and polices.
* Ensure that appropriate safety reporting systems are implemented in all clinical trials to fulfil strict regulatory requirements and ensure patient safety while participating in research.
* Ensure the rights of patients participating in research are protected (in accordance with the Data Protection Act and the principles of GCP).
* Ensure the researcher has the appropriate staff and facilities to conduct the study safely and effectively, in order to safeguard patient welfare and minimise organisational risk.
* Identify, assess and report serious incidences of research misconduct or fraud immediately to the Senior Clinical Trials Monitor, Deputy R&D Director and University Clinical Trials & Research Governance Manager in order to expedite the suspension/termination of the trial and safeguard patient welfare. Advise and implement any corrective action following identification research misconduct/fraud.

**Statutory Inspection*** Assist in the preparation for statutory inspection of NHS Lothian or the University by the MHRA (Medicines and Healthcare products Regulatory Agency) or any other external body as appropriate.
* Ensure NHS Lothian and University policies and procedures are compliant with the research legislation and are implemented.
* Support preparation by researchers and institutions for inspection and ensure all documentation is in place.

**Education*** Contribute to planning, development and delivery of research governance training packages for multidisciplinary researchers in Edinburgh to ensure that researchers are aware of and understand the legal requirements for carrying out clinical research.
* Keep up to date with changes in research legislation and guidance to ensure that accurate training and advice can be given.
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| 7a. EQUIPMENT AND MACHINERY |
| * The post-holder must have excellent IT skills and will spend a substantial amount of time working at a PC.
* The post-holder will use other pieces of standard office equipment (telephone, fax, printer, scanner).
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| **7b. SYSTEMS** |
| * The post holder will work extensively with: Word, Excel, PowerPoint, Outlook, Internet Explorer, Access, Publisher, Databases (web-based and Access), Adobe Acrobat Reader.
* The post-holder will write, update and work to ACCORD Standard Operating Procedures.
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| 8. ASSIGNMENT AND REVIEW OF WORK |
| * The post holder will work closely with the Senior Clinical Trials Monitor and be assigned work according to the needs of NHS Lothian and the University. Duties will be performed without direct supervision.
* The post holder’s work will be generated from the research activity within Edinburgh and the post is self-directed in terms of time and workload management.
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| **9. DECISIONS AND JUDGEMENTS** |
| * The post holder will make autonomous professional decisions on a daily basis.
* The post holder will apply the level of monitoring to each trial according to a risk assessment and must make informed decisions on the level of risk the trial proposes to patient safety and to the organisation.
* The post holder must be conversant with all trial protocols and make an assessment as to whether the protocol is being followed and whether researchers are conducting the research in accordance with the relevant legislation and approvals. This will involve making judgements from patient medical notes, trial data and interviews with researchers.
* Where non-compliance, research fraud or misconduct has been identified, the post holder must assess the impact of this in each case and make a decision on the corrective action to be taken, in consultation with ACCORD senior managers. Decisions may have to be made immediately to ensure patient safety. In serious cases the post holder may have to inform the R&D Director and ultimately the Regulatory Authority.
* The post holder must be able to interpret complex legislation and relay this information to researchers at all levels in a way that is appropriate to each individual. This will involve making judgements on the individual’s current knowledge and deciding what additional information they require to ensure accurate, concise training is given.
* The post holder must have a sound working knowledge of all research legislation and also the relevant University and NHS Lothian polices so that they can make autonomous, informed judgements on the sections of legislation that apply to any particular trial to provide bespoke advice and guidance in a complex and changing environment of regulated clinical research.
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| 10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB |
| * Encouraging change within NHS Lothian and the University to evolve a new research culture, ensuring researchers appreciate the importance and view as a priority the implementation of standards of good practice and research governance in their research;
* Understanding a dynamic and evolving legislative environment and contributing towards adapting policies for implementation of the requirements.
* Dealing with difficult situations involving senior researchers that require tact and diplomacy e.g. communication of negative findings during a monitoring visit.
* Performing consistently using high levels of concentration to review and assess large volumes of detailed trial information.
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| **11. COMMUNICATIONS AND RELATIONSHIPS** |
| **Internal communication*** NHS Lothian R&D Director, R&D Deputy Director and R&D Governance Manager;
* University of Edinburgh Clinical Trials & Research Governance Manager, Research Governance Manager
* Senior Clinical Trials Monitor;
* ACCORD QA Manager;
* Other ACCORD staff;
* Clinical research units staff e.g. WTCRF, ECTU;
* Clinical Trials pharmacy staff;
* Investigators and researchers across Edinburgh.

**External*** Research Ethics Committees;
* MHRA;
* External Sponsor organisations (external NHS Boards and Universities);
* External researchers;
* Participation in professional meetings/conferences related to the management and regulation of clinical trials.
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| **Modes of communication*** Telephone and email (daily);
* Mentorship, support and delegation (daily);
* Committees or group meetings (fairly regularly);
* Face-to-face meetings with individuals (regularly);
* Presentations to groups e.g. highlighting new developments (occasionally).
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| **12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB** |
| **Physical*** Travelling around Edinburgh and UK sites on a regular basis, including visiting NHS Lothian and University of Edinburgh premises;
* Working for long periods with a PC;
* Requirement to be flexible with working hours to fit monitoring visits in with researchers clinical commitments.

**Mental*** Frequent prolonged periods of concentration are required on a daily basis in order to assess, review and verify source data documents, ensuring that all patient trial data are correct and complete;
* Maintenance of precise and accurate study monitoring records;
* Recognising and responding to ethical issues that might arise during a study;
* Developed leadership and responsibility skills;
* Possibility of frequent direct and indirect interruptions from study site staff and multidisciplinary team;
* Adapting to unfamiliar surroundings during monitoring visits in a variety of hospital and academic settings.

**Emotional*** Communicating complex and sensitive issues with the research team that require tact, diplomacy and negotiating skills;
* Possible exposure to verbal hostility;
* Participating in statutory inspections and audits with a sound understanding of the implications for NHS Lothian and University future compliance and sustainability;
* Exposure to clinical information may be distressing at times.

**Environmental*** Working for long periods with a PC;
* Working in large, busy, shared office;
* Work requiring intense concentration often in less than desirable conditions when monitoring.
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| **13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB** |
| * University life sciences or nursing degree;
* Minimum of three years experience in clinical trial monitoring;
* Trained in ICH GCP, a sound working knowledge of the Research Governance Framework for Health and Community Care, Medicines for Human Use (Clinical Trials) Regulations, Adults with Incapacity (Scotland) Act, Data Protection Act, Governance Arrangements for Research Ethics Committees and Human Tissue Act;
* Excellent communication skills with a proven ability to work effectively as part of a team and independently;
* Strong listening and interpersonal skills;
* Analytical skills to relate legislation and good practice to particular research scenarios;
* Time management skills and ability to prioritise workload;
* Self motivation, showing initiative and good judgement;
* Ability to problem solve and make decisions;
* Excellent team working skills with ability to work using own initiative;
* Good writing skills;
* IT Skills (including the use of Access databases, Word, Excel, email and the internet).
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| **14. JOB DESCRIPTION AGREEMENT** |
| A separate job description will need to be signed off by each jobholder to whom the job description applies.Job Holder’s Signature: Head of Department Signature: | Date:Date: |