Hull and East Yorkshire Hospitals NHS
NHS Trust

HULL AND EAST YORKSHIRE HOSPITALS NHS TRUST
CLINICAL GOVERNANCE DIRECTORATE
RESEARCH AND DEVELOPMENT

Job Description

POST TITLE: Clinical Trials Monitor

GRADE: A4C Band 6

RESPONSIBLE TO: Research & Development Manager

ACCOUNTABLE TO: Director of Research & Development

JOB SUMMARY

The post holder will ensure that all HEY Trust sponsored clinical trials with investigational medicinal products (IMPs) are conducted according to;

- The UK Policy Framework for Health and Social Care Research
- ICH E6 Good Clinical Practice for clinical research
- Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) which transposed EU Directive 2001/20/EC into UK law and was effective from 01.05.04.
- Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006/1928) which transposed EU Directive 2005/28/EC into UK law and became effective from 29.08.06
- And subsequent Statutory Instruments 2006/2984, 2008/941, 2009/1164 and 2010/1882
- Human Tissue Act 2004, Data Protection Act 1998, Mental Capacity Act 2005.
- R&D GCP Standard Operating Procedures (SOPs)
- Relevant HEY Trust policies
- The clinical trial protocol

The post holder will also be responsible for conducting GCP monitoring for HEY-sponsored non-IMP trials and for some research studies sponsored by other non-commercial organisations being undertaken within the Trust.

KEY FEATURES OF THE ROLE

Responsibilities:

- Facilitating investigators where necessary in the completion of the IRAS application form in particular the MHRA clinical trial authorisation application form and study documentation e.g. the protocol, patient information sheet, informed consent form and GP letter.
- Facilitating investigators with the MHRA and ethics queries and requests prior to them granting clinical trial authorisation and ethics favourable opinion.
- Identifying studies to be monitored by using the research database EDGE.

- Working with investigators and Research Delivery Unit (RDU) Leads to issue Confirmation of Capability and Capacity prior to the start of the trial.
- To keep monthly summary reports of all Trust-sponsored IMP trials monitored to keep abreast of new trials to be monitored.
- To provide a record to aide in the risk assessment of trials to determine monitoring priorities.
- To organise, prepare, conduct, report and follow-up monitoring visits according to the GCP monitoring standard operating procedure.
- To escalate issues of non-compliance to the QA and R&D Manager as approptiate following Trust SOPs and monitoring vist report forms.
- To assist the QA and Training Manager in producing reports on request for the Trust Sponsor Oversight Committee (SOC).
- To train and facilitate investigators to understand the requirements for conducting clinical trials with medicinal products according to ICH GCP and the UK clinical trial regulations.
- To arrange monitoring visits with the chief/principal investigator and other study researchers.
- To perform monitoring visits at the department in which the clinical trial is being conducted and at CHH and HRI pharmacy, laboratories and any third party vendor in accordance with the processes and standards listed in CTIMP/non-CTIMP Monitoring Standard Operating Procedures.
- To perform regular monitoring visits throughout the duration of the trial; pre-study, during the trial and to close down a trial.
- To send out monthly monitoring reports to investigators and pharmacy at the end of every month and to chase up the completion and return of the reports to R&D.
- To check through the monthly monitoring reports for clarity and completion.
- To raise and resolve any queries with investigators concerning monthly monitoring reports.
- To cross-check investigator and pharmacy monthly reports and to resolve any queries with investigators or pharmacy staff.
- To update departmental spreadsheet as monthly monitoring reports are received.
- To advise and facilitate investigators in the set-up of the Trial Master File (TMF).
- To advise investigators in the compilation of the patient data (case report) forms.
- To advise investigators where necessary of the amendment notification procedure according to R&D GCP SOPs. This includes non-substantial and substantial amendments to the trial protocol.
- To advise investigators where necessary of the urgent safety measures defined by the MHRA.
- To help investigators when requested with the completion of the notification of amendment form.
- To check version control should the trial amendment involve amending trial documents (e.g. protocol, ICF, PIS) and that the *latest approved versions* of these documents are being used and examples filed in the TMF (according to R&D GCP SOPs).
- To train and advise investigators in the safety reporting procedures according to the R&D GCP standard operating procedure.

- To analyse, process and report the SAE/SAR/SUSAR reports within 24hrs of arriving at the R&D department according to the GCP safety reporting standard operating procedure.
- To raise and resolve any queries raised by the R&D Directors review of serious event reports with investigators.
- To forward SUSAR (and relevant SAE/SAR) reports to the MHRA and Ethics Committee (EC) within the required time frame
- To up-date the R&D summary tables and appropriate database of all serious events that are reported.
- To advise and facilitate investigators in the completion of the developmental safety update report (DSUR) for the MHRA and the annual progress report for the EC.
- To advise and facilitate investigators in the completion of the end of trial declaration form and submission of the report to the MHRA, REC and Trust.
- To facilitate the QA/training manager to improve and keep up-to-date the GCP standard operating procedures and GCP documentation used by investigators and for monitoring purposes.
- To facilitate the QA manager in the compilation of any GCP compliance reports and other information requests for the MHRA.
- To aid the QA manager to notify the MHRA in writing of any serious breach of GCP, within 7 days of becoming aware of that breach.
- To assist R&D in the preparation and during inspections by the MHRA and addressing findings during the follow-up of an inspection.
- To assist in the audit & monitoring of departmental audit reports.

Knowledge and Skills

- Competent to establish ICH-GCP procedures to ensure that the Trust meets the legal requirements of the UK clinical trial regulations for non-commercial Trust-sponsored IMP clinical trials.
- Competent to establish ICH-GCP procedures to ensure that the Trust meets the NHS requirements of the UK Policy Framework for Health and Social Care Research for Trust-sponsored non-IMP clinical trials.
- Competent to design and produce SOPs, ICH-GCP working forms and monitoring visit report forms.
- Competent to design, manage and produce systems and processes in the establishment of a TMF for Trust sponsored IMP/non-IMP trials.
- Able to monitor Trust-sponsored IMP/non-IMP clinical trials according to the established ICH-GCP procedures to ensure that these studies are conforming to ICH-GCP standards.
- Able to manage, organise and carry out on-site monitoring visits to ensure all aspects of ICH-GCP procedures are undertaken using appropriate systems and processes.
- Able to identify specific trial ICH-GCP non-compliance and manage and develop action lists to ensure compliance.
- Able to advise, encourage, support and ensure actions from monitoring visits are addressed and resolved by investigators and therefore ensure compliance with GCP.

- Able to design systems and processes for highlighting and recording any issues of ICH-GCP non-compliance.
- Competent in the management and production of reports reflecting the status of research monitoring for on-going active research within the Trust.
- Adept in reviewing and up-dating all relevant ICH-GCP documentation as and when necessary.
- Competent in providing advice, training and facilitation to clinical research staff when trials receive an inspection from the MHRA thereby ensuring adherence to ICH-GCP and the UK clinical trial regulations.
- Competent in teaching and training researchers and R&D dept staff in the GCP processes required to conduct a Trust sponsored IMP clinical trial to the mandatory MHRA standards.
- Competent in teaching and training researchers and R&D staff in the GCP processes required to conduct a Trust sponsored non-IMP trial to the UK Policy Framework for Health and Social Care Research which is mandatory for the NHS.
- To maintain own knowledge of ICH-GCP standards and other similar UK regulations governing good healthcare research.
- Capable of compiling a variety of monitoring visit reports.
- Able to conduct protocol driven monitoring for non-commercial research sponsored by other organisations (other Trusts/Universities/Research network etc) being undertaken within the Trust to ensure compliance with the UK Policy Framework for Health and Social Care Research, ICH GCP and the UK regulations.
- Capable of ensuring effective systems and processes are developed for the monitoring of non-commercial on-going research projects within the Trust.
- Supervise, train & support R&D staff members as an when necessary
- A specialist knowledge of healthcare research government legislation, specifically :
    - ICH-GCP E6 (for clinical research)
    - EU Directives 2001/02/EC & 2005/28/EC – The Medicines for Human Use (Clinical Trials) Regulations and subsequent EU Directives making amendments to the regulations.
    - Medicines and Healthcare Products Regulatory Authority (MHRA)
        - UK Policy Framework for Health and Social Care Research (2017)
    - Eudract data base
- A working knowledge of healthcare research government legislation specifically:
    - Human Tissue Act (2004)
    - Mental Capacity Act (2005)
    - Declaration of Helsinki (1996/2000)
    - Data Protection Act 1998 & Caldicott Guardian principles
    - NIHR UK Clinical Research Networks (UK CRN),
    - Health Research Authority (HRA) and National Research Ethics Committee (REC),
    - Integrated Research Application System (IRAS)
- A broad knowledge of Trust
    - policies and procedures
    - departmental protocols pertaining to research and development
    - research agreements, informed consent principles, and clinical and non-clinical indemnity for research.

- Ability to advise, communicate and offer specialist training effectively across a range of divisions, services and agencies both internal and external to the Trust.
- Capable of providing information, education, training and advice to a variety of clinical and non-clinical staff across various levels.
- Ability to promote awareness of GCP and the government healthcare research legal requirements.
- Able to support the QA Manager in the delivery of the GCP training for the NIHR Clinical Research Network.
- Able to project plan as required.
- Willingness and ability to share relevant information and experience with staff in partner NHS and academic organisations.
- Able to work autonomously and undertake a specialist role for trial monitoring within the Trust.

Effort and Environment

- **Physical effort** – Every day – sustained periods of time at a desk and computer screen
- **Mental effort** – Everyday requires high and sustained levels of concentration, to comprehend and respond to issues in researchers protocols and information leaflet, supportive documents, resource information, contracts etc. ensuring compliance with healthcare research government legislation, identifying information relevant to researchers
- **Emotional effort** – Active negotiation with researchers about documentation and standards of research proposals. First contact with researchers and organisations working to tight and demanding timescales. Skills to effectively manage people working within R&D department
- **Working conditions** – Office environment

Health and Safety

In addition to the Trust's overall responsibility for your health and safety you have a personal responsibility for your own health and safety. As such you are required to inform your line manager of any safety issues that you identify, that could affect you or others in the workplace. You must co-operate with management and colleagues at all times in achieving safer work processes and work places, particularly where it can impact on others.

As a Trust employee you will be trained in the correct use of any equipment provided to improve safety and health within the Trust. You are required to use the equipment when necessary and as instructed which will include checking the equipment is safe to use, prior to its use and must report any defects immediately to your line manager.

You are responsible for the implementation and adherence to Trust safety policies and procedures for areas within your remit. You are required to ensure suitable and sufficient risk assessments are completed for all areas within your remit. The controls identified must be evaluated and implemented where necessary.

You are required to review all risk assessments periodically and particularly when staffing and/or equipment changes, monitoring the effectiveness of any control measure implemented.

You are to ensure suitable and sufficient equipment is provided to sustain the health and safety of staff, patients and visitors to areas within your remit.

HULL & EAST YORKSHIRE HOSPITALS TRUST

PERSON SPECIFICATION

JOB TITLE: **CLINICAL TRIALS MONITOR**

DEPARTMENT: **RESEARCH & DEVELOPMENT**

AREAS	ESSENTIAL	DESIRABLE
QUALIFICATIONS	A masters or higher degree or equivalent experience or training to master's level equivalent	Teaching or delivery of training PhD in relevant topic Member of ICR
EXPERIENCE	More than 3 year's relevant experience in the NHS or appropriate external healthcare organisation. At least 2 year's research-related experience. Evidence of continuous professional development and of acquiring new skills/knowledge in the past 3 years. Legal or other work requiring understanding of contracts or similar documents. Current GCP training Training in or experience of presenting to groups	Experience facilitating multidisciplinary teams. Project Management Responsibility for performance management and meeting challenging targets. Work involving budget control or financial management. R&D management in the NHS, University or industry. Intellectual property or technology transfer work. Information management. Teaching/training experience
SKILLS, KNOWLEDGE AND ABILITY	The UK Policy Framework for Health and Social Care Research. EU Directives 2001/20/EC & 2005/28/EC - The Medicines for Human Use (Clinical Trials) Regulations and subsequent amendments Medicines and Healthcare Products Regulatory Authority (MHRA). UK Policy Framework for Health and Social Care Research (2017) Eudract data base. Research methodologies.	NHS Policies and organisational structures. Proficiency in MS Excel, Access. Working knowledge of NHS financial processes Presentation skills Human Tissue Act (200) Mental Capacity Act (2005) Declaration of Helsinki (1996/2000) GDPR, Data Protection Act 2018 & Caldicott Guardian principles UK Clinical Research Network (UK CRN), Health Research Authority

	Proficiency in: MS Word PowerPoint. Excellent written and oral communication skills.	(HRA) National Research Ethics Service (REC), Integrated Research Application System (IRAS)
PERSONAL ATTRIBUTES	Team player. Proactive approach to work, and able to work on own initiative. Able to prioritise and manage own and others time effectively. Able to understand and explain complex issues. Able to communicate effectively at all levels. Willing to develop and learn new skills.	
OTHER REQUIREMENTS	Flexible. Able and willing to work across all sites in the Trust. Able to travel. Able to work to facilitate the achievement of Directorate–wide responsibilities. A pleasant, positive temperament and manner. A resilient, assertive character. A practical and realistic approach to work.	