



JOB DESCRIPTION

POST NIHR Alder Hey Clinical Research Facility (CRF) Operational Manager

ACCOUNTABLE TO Director of Research

REPORTS TO AHCRF Director

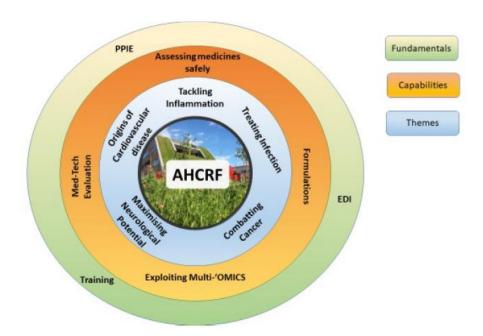
ACCOUNTABLE FOR NIHR Alder Hey Clinical Research Facility

AGENDA FOR CHANGE BAND 8a

The NIHR Alder Hey CRF (AHCRF) is based in the heart of Alder Hey Children's Hospital. It is a purpose-built, cutting-edge facility providing a high quality, clinical space in which children and young people can take part in clinical research safely and effectively, according to robust and ethically approved protocols. The facility is staffed by paediatric research nurses, a research play specialist, clinical trial pharmacists and other support staff. The AHCRF team works with all research related staff to provide a robust service for the facilitation and delivery of safe and effective clinical research. Priority areas for AHCRF are experimental medicine, commercial and non-commercial early phase trials and studies of high intensity and risk, as well as late phase clinical trials. Priority themes, key capabilities, and underpinning principles are shown below







The CRF Operational Manager will be responsible for developing and implementing an effective operational strategy that deliver the short, medium and long term objectives of AHCRF, based on the 2022 renewal. These reflect local and national needs and were designed to deliver high quality research and ensure the best use of resources. The post holder will also work closely and collaboratively with senior colleagues within the Clinical Research Division (CRD), in particular the Research Governance Manager and Research Matron to support the effective setup and delivery of studies within the CRF, and the General Manager and Head of Nursing for Research, to optimise the support for and integration of the CRF within the whole of the research architecture of Alder Hey.

Key Relationships

Internal: CRF Director, CRF Co-Director, Research Theme Leads, Director of Research, CRF Operational and Clinical Research Teams, Head of Research Operations, Head of Nursing for Research, General Manager, Research Governance Manager, Research Matron.





External: Liverpool University Hospital Foundation Trust Clinical Research Unit (LUHFT CRU) team, NIHR North West Coast Clinical Research Network (CRN), Experimental Arthritis Treatment Centre for Children (EATC), HEIs including University of Liverpool, LJMU, UCLan and Edge Hill University, UK CRF Network, NIHR Central Commissioning Facility, Department of Health and Social Care, Commercial sector, Starting Well Programme, Neuroscience & Mental Health Programme, NIHR Great Ormond Street Hospital Biomedical Research Centre (GOSH BRC) Paediatric Excellence Initiative

Main duties and Responsibilities

Communication

- 1. To champion the CRF project to executives, senior managers and clinicians within the Trust.
- 2. To engage with key groups and individuals across both the Trust (internal theme leads, research active departments and investigators), and external academic and commercial partners, to ensure ongoing collaborative research relationships are established, and effective project delivery achieved.
- 3. To oversee liaison with pharmaceutical companies and clinical research organisations during the set-up, interventional and follow up phases of commercial studies.
- 4. Develop relationships with other CRFs across the UK CRF Network in order to operationalise collaboration on projects or wider initiatives, in particular the LUHFT CRU.
- 5. To develop and maintain links with key partners and initiatives including the North West CRF Alliance, GOSH BRC Paediatric Excellence Initiative and CRF Managers Network.
- 6. To routinely report performance information, including progress against NIHR short, medium and long term objectives, to key internal and external committees.
- 7. Deliver formal presentations to large groups of stakeholders.

Analytical skills

- 8. Analysis of CRF performance data to determine trends and patterns e.g. analysis of proportion of early phase and experimental medicine trials over time, and collate these data into reports (e.g. Trust committees, NIHR annual reports)
- 9. Interpretation of trends and patterns to inform options to progress.
- 10. Use of expert judgement to recommend and/or implement options.





- 11. Manage the publicity and promotion of the CRF including planning and coordination of open days and events. Seek opportunities to promote the CRF as a centre of excellence.
- 12. Oversee the development and on-going maintenance of the CRF website and social media accounts (i.e. X®) as channels for both internal and external communication.

Planning and organising skills

- 13. Responsible for the day-to-day running of the non-clinical aspects of the CRF, including facilities and information management.
- 14. Taking into account the AHCRF objectives, Trust's overall strategy, Trust research strategy, develop and implement a range of plans to improve CRF engagement and performance across departments and services across the Trust.
- 15. Be responsible for the operational delivery of the research programme.
- 16. Take action to address project underperformance.
- 17. In conjunction with the CRF Director, Deputy and senior management team, plan and produce the CRF annual report, quarterly reports to NIHR CCF, and ensuring that planning requirements are regularly updated for the forthcoming six months.

Physical skills

18. Standard keyboard skills.

Responsibility for policy/service development

- 19. Contribute to the development of clinical and research policies and procedures.
- 20. Responsibility for ensuring that policies relating to the CRF are fit for practice and are implemented across the Trust.

Responsibility for financial and physical resources (detail below)

(Is the post holder responsible for financial resources?)

21. Work with the senior management team to develop and implement an income strategy for the CRF to ensure the long-term financial stability of the CRF.





- 22. To have responsibility for the departmental budget and physical resources and their effective utilization.
- 23. Responsible for management of the CRF budget.
- 24. Provide reports to divisional and Trust committees on financial matters relevant to the CRF.
- 25. Liaise with investigators and research support team to provide estimated costs for proposed CRF research studies.
- 26. Manage the ordering of medical equipment, supplies, services and equipment, ensuring that competitive quotes are obtained, and resources are effectively and efficiently utilised.
- 27. Provide regular reporting to NIHR on utilisation of funds.
- 28. Responsible for the on-going management of the CRF's medical equipment. Develop and maintain inventories appropriate for good resource management and ensure that systems are in place for safety testing, servicing and maintenance as appropriate.
- 29. Responsible for procurement of new equipment, furniture & fittings and ensure that purchases are underpinned by maintenance contracts where appropriate.
- 30. Liaison with Estates and external suppliers in planning and implementing any repairs, improvements or other building works.
- 31. Jointly with the Matron, be responsible for the Health and Safety of patients, visitors and staff ensuring that all incidents, accidents and hazards are reported according to the Trust's incident reporting mechanisms and that the CRF provides a safe environment for research. Conduct risk assessments where appropriate.
- 32. Be responsible for undertaking regular business continuity planning for the CRF and implementing any necessary changes, with support from the wider team.

Responsibility for human resources (detail below)

- 33. Develop and co-ordinate the established national online teaching/training programme.
- 34. Promote sharing of best practice through regular team meetings and externally with other UKCRFs
- 35. Co-ordination of placement staff and students.
- 36. Supervision of external visitors and contractors to CRF.

Responsibility for information resources (detail below)

- 37. Responsible for updating and maintaining CRF related information e.g. ward occupancy.
- 38. Responsible for quality assurance of CRF related data on Trust systems.





- 39. Responsible for creating reports to support performance and reporting.
- 40. Collation of data for, and writing of, NIHR annual report

Responsibility for research and development (detail below)

- 41. Routinely oversee the operational aspects of clinical R&D activity within the CRF in conjunction with the matron.
- 42. Conduct customer satisfaction questionnaires, user and patient surveys to monitor departmental performance and develop action plans to address any issues raised.
- 43. Provide assurance that medical equipment is appropriately tested.
- 44. Maintain a thorough working knowledge of current research governance and EU Clinical trial legislation, guidance and policies and ensure these are adhered to by staff in conjunction with the research governance manager
- 45. Maintain a working knowledge of issues relating to delivering clinical research studies in a paediatric setting.
- 46. Maintain awareness of local Trust policies relating to research and its governance and ensure all staff comply with these.





Our values:



We pride ourselves on the quality of our care, going the extra mile to make Alder hey a safe and special place for children and their families.



We are committed to continually improving for the benefit of our patients.



We are open and honest and engage everyone we meet with a smile.



We show that we value every individual for who they are and their contribution.



We work across the Alder Hey community in teams that are built on friendship, dedication, care and reassurance.





Values Based Behaviour's

Respect:	We show that we value every individual for who they are and their contribution
Excellence	We pride ourselves on the quality of our care, going the extra mile to make Alder Hey a safe and special place for children and their families
Innovation	We are committed to continually improving for the benefit of our patients
Together:	We work across the Alder Hey community in teams that are built on friendship, dedication, care and reassurance
Openness:	We are open and honest and engage everyone we meet with a smile





PERSON SPECIFICATION

Job Title

AFC Band

		ESSENTIAL	DESIRABLE
1.	Education and Training	 Educated to masters level in a subject relevant to the role or equivalent relevant experience. Project management qualification or equivalent relevant experience. 	Valid GCP certificate
2.	Experience of	 Management within a clinical research environment. Working with clinicians and other health care professionals Engaging with commercial and academic partners. Experience of effective budgetary management and control, including achieving annual targets on a regular basis. Managing organisational change. Presenting to large groups of staff or members of the public. 	 Management experience within a paediatric setting within the NHS
3.	Knowledge of	 Research practice within the NHS. The NIHR and its KPIs. Operations and project management. Financial principles and processes. IT systems and processes for research and performance management. 	 Paediatric research practice with the NHS EDI principles
4.	Skills	 Highly developed interpersonal and facilitation skills, with ability to gain and maintain credibility at all levels of the organisation, including with senior clinicians and external partners. Political awareness – ability to perceive impact of actions on the decisions and activities of others. 	

















	 Excellent organisational skills with the ability to respond effectively to multiple priorities Ability to interpret national guidance relating to research. Ability to analyse and interpret complex information. Ability to propose changes to practice and lead on service development. Ability to communicate with staff and colleagues at all levels Time management skills, able to meet deadlines, and work with several projects simultaneously. Excellent verbal and written communication skills and listening skills.
5. Personal Attributes	 Able to work independently. Composed and resilient. Team worker. Punctual and flexible across hours of work when required. Treats others with courtesy and respect at all times. Takes responsibility for own actions and promotes good team working.



Mandatory Statements

- 1. As an organisation which uses the Disclosure and Barring Service (DBS) Disclosure service, the Trust complies fully with the DBS Code of Practice and undertakes not to discriminate unfairly against any subject of a Disclosure on the basis of conviction or other information revealed. The Trust meets the requirements in respect of exempted questions under the Rehabilitation of Offenders Act 1974, All job applicants will be subject to a criminal record check from the Disclosure and Barring Service before an appointment is confirmed. This will include details of convictions cautions and reprimands, as well as 'spent' and 'unspent 'convictions. A criminal record will not necessarily be a bar to obtaining a position. A decision will be made depending on the nature of the position and the circumstances and background of the offences.
- 2. The Trust is pro-diversity and anti-discrimination, and takes a zero tolerance approach to racism, discrimination, victimisation, bullying or harassment. The Trust is committed to treating people equally, whether they are patients, colleagues, suppliers or other customers. We expect all of our families and staff to feel valued and respected.
- The Trust is committed to promoting an environment that embraces diversity and promotes equality of opportunity. Staff are expected to apply the values of respect, excellence, innovation, togetherness and openness in all that they do.
- 4. In the course of your duties you may acquire or have access to confidential information which must not be disclosed to any other person unless in the pursuit of your duties or with specific permission given on behalf of the Trust. You must ensure that you handle personal information in accordance with the requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018
- 5. You are reminded that, in accordance with the Health & Safety at Work Act 1974, and subsequent legislation, you have a duty to take reasonable care to avoid injury to yourself and to others by your work activities, and are required to co-operate with the Trust in meeting statutory requirements.
- 6. You must ensure that you adhere to the Trust Infection Control policies and procedures at all times. You have a duty of care under the Health Care Act to prevent the spread of infection.
- 7. Within the NHS, good patient care is reliant on the availability of complete, accurate, relevant and timely data. The quality of information can limit the capability to make operational decisions about the way care is planned, managed and undertaken. Poor information quality can lead to poor decision making and may put service users at risk. High quality information means better, safer patient care. Where you are required to record data on systems, whether patient or staff data, or paper or electronic format you must ensure













My Alder Hey. My Values.

that is it up to date, accurate, complete and timely. You have a responsibility to ensure that you feel sufficiently knowledgeable about the system you are asked to use and what is required of you in order to fulfil your task accurately. Where an error is created or discovered by yourself on any system which you cannot rectify, you must contact the relevant helpdesk / system owner or your Line Manager. Please read the Data Quality and Information Governance Policies located on the Intranet and ensure you understand your responsibilities.

- 8. Alder Hey Children's NHS Foundation Trust is committed to safeguarding and promoting the welfare of children and young people and expects all staff and volunteers to share this commitment. Staff have a responsibility to ensure they are aware of specific duties relating to their role and should familiarise themselves with the Trust's safeguarding and child protection procedures; regular safeguarding and child protection training updates are mandatory for all staff.
- 9. All individuals will have some risk management responsibilities with which you are required to comply, for details of your responsibilities please refer to the current Risk Management Strategy which is available on the intranet and in the local strategies folder.
- 10. You must comply with all Trust policies and procedures and attend all necessary mandatory training.
- 11. As an employee of the Trust you will be accountable for the data entered into records and systems. It is very important that the Trust records the most up to date patient demographic details, including full name, D.O.B., address, contact number, NHS number, GP and GP Practice. This is not only to fulfil our legal obligation under Data Protection legislation, but it is also crucial in ensuring patient safety. All staff should take ownership of records that are accessed and take the opportunity to check that the data held is correct.
- 12. This document provides an outline of the main responsibilities of the post. It is not intended to be an exhaustive list of duties.
- 13. Your job description will be subject to regular review with your Line Manager.