Faculty of Health, Medicine and Social Care

Job Description

Job Title:	Clinical Trials Unit Medical Director
Grade:	Clinical Academic
Job Family:	Academic
Work Base:	Chelmsford
Hours of Work:	Part time, 0.4 FTE
Responsible to:	Head of School of Medicine
Responsible for:	No line management responsibilities
Relationships and Contacts:	Senior Management Team of the Faculty Internal management and employees Head of School of Medicine Deputy Dean (Research and Innovation) NHS Research and Development Leads NIHR Clinical Research Networks External/regulatory bodies as appropriate
Job Purpose:	To undertake the medical leadership and development of the Clinical Trial Unit

Principal Accountabilities:

1. Provide clinical and strategic leadership for the ARCTU development program.
2. Offer support and guidance to the ARCTU Operations Director in meeting the CTU's ambition of gaining UKCRC registration within five years.
3. Lead the development of the ARCTU clinical study portfolio, taking on the role of chief investigator in a number of multi-centre studies.
4. Secure substantial research funding from NIHR funding streams.
5. Provide clinical input into funding applications and the development of study protocols for studies supported by ARCTU.
6. Build an extensive network of clinical collaborators, acting as principal investigator for high profile multicentre randomised controlled trials.
7. Be proactive in providing opportunities and mentorships for clinical researchers taking on the role of PI for the first time.

8. Take the lead in developing the pool of ARCTU CIs and PIs, setting clear expectations for the level of CTU involvement in each study.

9. Establish an ARCTU portfolio adoption process to ensure that all studies supported by the CTU contribute towards meeting it's strategic aims.

10. Provide strategic input and support to the ARCTU Operations Director in developing all ARCTU policies and procedures.

11. Take responsibility for overseeing safety monitoring procedures for all ARCTU studies.

12. Support external research studies taking on appointments on independent data monitoring committees and trial steering committees.

13. Supports the development of clinical academic/research training through the School of Medicine.

14. Take on senior appointments within the University and NHS partner organisations, keeping the ARCTU team up-to-date and aligned with all relevant developments and priorities.

15. Keep up to date with changes to the clinical research regulatory framework within the UK.

16. Build the profile of the ARCTU by taking a leading role in NIHR research networks or equivalent organisations.

17. Provide expert analysis and interpretation of data from ongoing studies and from the literature.

18. Build positive working relationships with internal and external stakeholders including funding bodies, the RDS, CRN, local R&D departments and sponsor representatives.

19. Demonstrate a commitment to delivering high quality research, providing clinical input into the preparation of regulatory submissions and standard operating procedures.

20. Generate high quality clinical research publications.

21. Represent the ARCTU at clinical and scientific meetings.

22. Support the development of an ARCTU PPI strategy.

23. Ensure the ARCTU development is in line with the NHS long term plan and the NHS campaign for a greener NHS.

24. Comply with Data Protection Act 2018 and GDPR requirements in all working practices maintaining confidentiality, integrity, availability, accuracy, currency and security of information as appropriate. Take personal responsibility for all personal data within own working environment.

25. Such other duties temporarily or on a continuing basis, as may reasonably be required, commensurate with your grade.

This is a description of the job as it is presently constituted. It is normal practice to review periodically job descriptions to ensure that they are relevant to the job currently being performed, and to incorporate any changes which have occurred or are being proposed. The review process is carried out jointly by manager and employee and you are therefore expected to participate fully in such discussions. In all cases, it is our aim to reach agreement to reasonable changes, but where it is not possible to reach agreement, we reserve the right to make reasonable changes to your job description which are commensurate with your grade after consultation with you.

October 2023

Faculty of Health, Medicine and Social Care
Clinical Trials Unit Medical Director
Person Specification

ESSENTIAL	DESIRABLE
ACADEMIC/PROFESSIONAL QUALIFICATIONS • Qualified physician, holding a current clinical appointment at consultant level of at least 0.2 FTE • GMC registered with a wide experience in the delivery of clinical care in the UK	• PhD/DPhil in a scientific or medical discipline (highly desirable)
EXPERIENCE • Extensive experience of working with Clinical Trials Units to deliver high quality research • Extensive experience of leading multi-centre randomised controlled trials acting as CI and PI, including clinical trials of investigational medicinal products • Extensive experience of delivering clinical studies which are eligible for NIHR portfolio adoption • Experience of drafting study protocols and contributing to the development of other 'essential documents' • A track record of leading on and securing substantial research funding through the competitive peer review process • Experience of working within a University research environment or of collaborating with University colleagues • Experience of contributing at a senior level to NHS or University strategic committees • A track record of building effective scientific collaborations • Experience of being a member of a Trial Steering Committee or Data Monitoring Committee • Experience of conducting systematic reviews • Track record of producing high quality publications	

• Experience of attending HRA Research Ethics Committee meetings as part of the research team	
KNOWLEDGE/SKILLS • Understanding of the UKCRC CTU registration criteria • Knowledge of the UK clinical research regulatory framework • with up to date, Good Clinical Practice training	
PERSONAL QUALITIES/DISPOSITION • Ability to negotiate and influence with diplomacy to achieve results • Demonstrated strategic leadership ability with a strong customer focus • Excellent communication skills, a positive attitude with a willingness to embrace a challenge	
OTHER • Member of a national clinical research network • Experience of presenting at scientific conferences and meetings • Experience of delivering training in research study protocols • Willingness to travel in UK and worldwide on occasion • Committed to equality and diversity, our Health and Safety policies and procedures and our University's values • Compliance to Data Protection Act 2018 and GDPR principles/ requirements	

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