

Research & Innovation: Clinical Research Practitioners Strategy.



This strategy applies to all clinical research practitioners (CRPs) working across UHL research infrastructure, including the NIHR Biomedical Research Centre, the NIHR Clinical Research Facility, and the NIHR Patient Recruitment Centre.

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Thank you:

This strategy is based on feedback received by the regional CRP research workforce. A huge thank you goes to the East Midlands Clinical Research Network team for supporting the collection of data via a regional survey.

N&M: Nurses and Midwives

Abbreviations used within this document:

AHPs: Allied Health Professionals

AHCS: Academy of Health Care Science R&I: Research and Innovation

CRN: Clinical Research Network UHL: University Hospitals of Leicester

DMU: De Montford University

UoL: University of Leicester

Introduction

The workforce delivering research has long been made up of staff registered as part of a professional body as well as those staff not belonging to a registered healthcare body. This 'non-registered' group that drives and supports the delivery of research without a distinct professional registration has gained momentum over the last few years culminating in the formation of a dedicated profession with a directory and register, the Clinical Research Practitioner (CRP).

The CRP community has been a key driver in the delivery of studies during the pandemic and we would not be where we are today without this.

The role of CRPs in the future research delivery workforce will be significant, as outlined in the UK Government Policy Paper and Implementation Plan, Saving and improving lives: the future of UK clinical research delivery. In the face of both high demand for delivery of research and significant workforce challenges, particularly in nursing, CRPs have been identified as part of the solution

The Clinical Research Network East Midlands has helped shape the national agenda here and continues to be the leading region for registered and those on the directory, we are keen to see the growth of CRPs and are fully supportive of this UHL strategy.



Dan KumarDeputy Chief Operating Officer CRNEM



Antonella Ghezzi: Head of Research (N&M), UHL.

Scope of practice

The Clinical Research Practitioner role involves defined clinical responsibilities and skills within the boundaries of clinical and health related research delivery (AHCS 2021). The role is distinct from a NMAPS (Nursing, Midwives and Associated Healthcare Professionals) role and works in complement with research nurses and others as part of the clinical research delivery team.

The term Clinical Research Practitioner (CRP) refers to professionals involved in the delivery of research that involves a duty of care relating to participants in studies. This scope of practice is relevant for those eligible to register as a Clinical Research Practitioner with experience as an unregistered or previously registered practitioner.

The CRP works in research delivery roles that involve direct contact with patients or other study participants. CRPs are now identified as an occupational group in health and care in the UK by the UK Professional Standards Authority (PSA). CRPs account for 25% of the national clinical research delivery workforce.

CRPs are a vital part of the research workforce. They include research officers, research assistants, research health care assistants and support workers from a variety of allied disciplines such as psychology or mental health, as well as science and health related subjects. Their remit spans from working as independent practitioners, supporting the nursing clinical team, setting up and delivering research projects as well as supporting the R&I wider team in administering the research process.

This strategy emerged from a review of data collected from a regional survey which was sent by our local Clinical Research Network East Midlands. The survey was sent to 125 CRPs across the region, response rate was 30%.

The feedback received highlighted the importance of having a clear strategy which will support the employment, development and retention of talented staff.



Aim

The aim of this strategy is to create a supportive infrastructure for Clinical Research Practitioners at UHL which is based on your feedback.

Things you want to see:

- You want to see unified roles under the CRPs umbrella
- You want to see fewer and clearer job descriptions and person specifications which follow a defined career progression pathway
- You want to work in a clinical role as well as developing the administrative side of research
- You want to be recognised as an active member of the team, you told us you feel unregulated, invisible, unrecognised.
- You want to be a registered practitioner as well as having the opportunity to work in a non-registered role
- You want to see more training and development opportunities
- You want to see a roadmap for career advancement including how to achieve milestones
- You want to be able to work confidently on CTIMPs
- You want to further academic development
- You want clarity on the benefits of the NIHR CRP Register and the NIHR CRP Directory

Objectives

- 1. To define the role of the CRP and harmonise the banding structure as per Scope of Practice for CRPs (NIHR ref) including a review of all JDs and PSs.
- 2. To create a roadmap for career development including registration.
- 3. To identify learning and development opportunities for all including advanced clinical practice, leadership, management and clinical academic pathways.

Objective 1

At UHL we have a variety of roles which falls under the umbrella of CRPs. There is a national and local need to harmonise roles and to create a clearer structure, all R&I roles covering elements of research delivery including a patient facing element will be pulled under the umbrella identified as "Clinical Research Practitioners". The NIHR strongly support this view and reiterate that any member of the delivery team who is not registered with a governing body can be identified as a CRP.

This include:

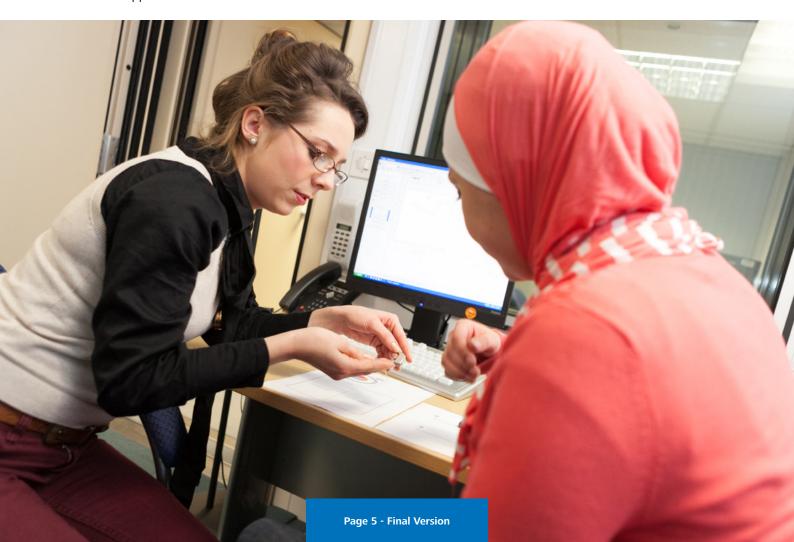
linical research assistants, health care assistants, research assistants, research officers, research support assistant, research support officers, senior health care assistants, senior research assistants, senior study support officers, support assistants/technicians, associates.

From 1st of April 2022, all new research roles will be embedded under the "Clinical Research Practitioner" umbrella and will follow the Scope of Practice Skills for Health career development scheme as over the page

Banding Structure

- **Band 1 Research Apprentice**
- **Band 2 Clinical Research Assistant**
- Band 3 Senior Clinical Research Assistant
- **Band 4 Assistant Research Practitioner**
- **Band 5 Clinical Research Practitioner**
- **Band 6 Senior Clinical Research Practitioner**
- Band 7 Advanced Clinical Research Practitioner/Lead Research Nurse/Research Manager
- **Band 8 Senior Research Manager**

JDs and PSs in Appendix



BAND 8

People at Ithis level of the career framework require highly specialised knowledge, some of which is at the forefront of knowledge in a field of work, which they use as the basis for original thinking and/or research. They are leaders with considerable responsibility, and the ability to research and analyse complex processes. They have responsibility for service improvement or development. They may have considerable clinical and/or management responsibilities, be accountable for service delivery or have a leading education or commissioning role. Indicative or Reference title: Senior Research Manager

BAND 6

People at this level require a critical understanding of detailed theoretical and practical knowledge, are specialist and / or have management and leadership responsibilities. They demonstrate initiative and are creative in finding solutions to problems. They have some responsibility for team performance and service development and they consistently undertake self development. Indicative or Reference title: Specialist/
Senior Research Practitioner

BAND 4

People at this level require factual and theoretical knowledge in broad contexts within a field of work. Work is guided by standard operating procedures (SOPs), protocols or systems of work, but the worker makes judgements, plans activities, contributes to service development and demonstrates self development. They may have responsibility for supervision of some staff. Indicative or Reference title: Assistant/Associate Research Practitioner

BAND₂

People at this level require basic factual knowledge of a field of work. They may carry out clinical, technical, scientific or administrative duties according to established protocols or procedures, or systems of work. Indicative or Reference title: Research Support Worker

BAND 7

People at this level of the career framework have a critical awareness of knowledge issues in the field and at the interface between different fields. They are innovative, and have a responsibility for developing and changing practice and/or services in a complex and unpredictable environment. Indicative or Reference title: Advanced Research Practitioner

BAND 5

People at this level will have a comprehensive, specialised, factual and theoretical knowledge within a field of work and an awareness of the boundaries of that knowledge. They are able to use knowledge to solve problems creatively, make judgements which require analysis and interpretation, and actively contribute to service and self-development. They may have responsibility for supervision of staff or training. Indicative or Reference title: Research Practitioner/NIHR Registered Research Practitioner

BAND 3

People at this level require knowledge of facts, principles, processes and general concepts in a field of work. They may carry out a wider range of duties than the person working at level 2, and will have more responsibility, with guidance and supervision available when needed. They will contribute to service development, and are responsible for self-development. Indicative or Reference title: Senior Research Support Worker/Senior Research Healthcare Assistants/Technicians

BAND 1

People at this level are at entry level, and require basic general knowledge. They undertake a limited number of straightforward tasks under direct supervision. They could be any new starter to work in the Health sector, and progress rapidly to Level 2. **Indicative or Reference title: Apprentice**

Objective 2

The Scope of Practice states that CRPs assessed by the Academy for Healthcare Science as meeting the required Standards of Proficiency will hold accredited registration and will be recognisable as autonomous and accountable professionals specifically within the context of delivering clinical and health related research, having the authority to make decisions and act in accordance with their own professional knowledge base.

Expectations of Clinical Research Practitioners will differ depending on education, training and experience, particularly with respect to their clinical knowledge and skills, and will not necessarily meet the requirements of every clinical research study protocol. However, according to study protocol, the clinical context and research delivery setting, all Clinical Research Practitioners involved in delivery will have a duty of care to study participants., When working in a clinical environment, they will be expected to hold appropriate training to be able to provide and monitor care and to actively liaise with statutory registered professionals assessing, planning, implementing and evaluating care.

At UHL, Clinical Research Practitioners will continue to have the opportunity to develop further skills and to obtain the "registered" status. In order to be eligible to register as a "NIHR Clinical Research Practitioner" the following pathway is available:



Assessment of current skills, experience and education (via the Academy for Healthcare Science).

Competency based practice which is aligned with the NIHR CRN EM competency package. Refer to https://crnemwfd.nihr.ac.uk/competency-framework

Supervisor/Manager statements to support clinical and academic development.



The CRP Directory was established in 2018. The Directory for Clinical Research Practitioners has been established to create a Community of Practice as a foundational step in defining the professional identity of this group.

Approval was given by the Professional Standards Authority for the AHCS to establish a new part of their accredited register for CRPs. The Register was launched in March 2021 and is now open for applications.

To find out more about the NIHR Directory and Register, and to apply https://nihr.ahcs.ac.uk/

The Directory and the CRP Register are supported by the DHSC, AHCS and the NIHR. The NIHR CRN Programme for growth and development of CRPs is a UK programme which is available to all.

TO SHOUT loud:



Since 2018, 1236 CRPs have joined the Directory
Since March 2021, 267 CRPs started the application process, 79 registered

Access to CRP register:

A review is currently underway that will lead to access to the register being offered to the current workforce who do not hold a degree, this might be temporary or possibly longer-term.

Refer to https://crnemwfd.nihr.ac.uk/clinical-research-practitioners/resources

Journey to registration:



Apply to the register

Eligibility:

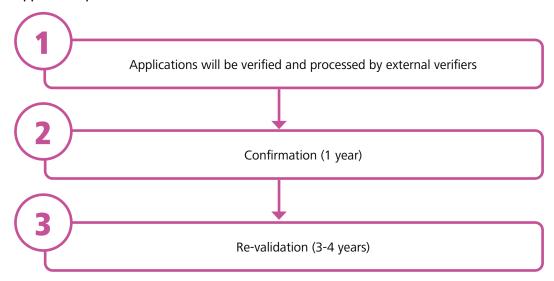
- 1. 1-2 years at CRP level
- 2. Current graduate
- 3. Meet all 16 standards of proficiency
- 4. Professional Responsibility
- 5. Skills, behaviours, knowledge
- 6. Leadership

The Application Process will become part of the appraisal of professional development

Process:

- Demonstrate you meet Standards of Proficiency and upload 5 documents
- Documented Assurance of Practice Development
- Reflective Statements including professional responsibility, working across boundaries and leadership
- Confirmation form by line manager referring to: competency framework, knowledge and skills development
- Portfolio of evidence

Application process



Each applicant and confirmer will contribute to:

- 1. Support the development of the CRP profession and CRP community
- 2. Promotes CRP role
- 3. Raise the profile of CRPs
- 4. Support integration of multidisciplinary teams

Objective 3

Training and development will include:

- Practice Skills (CRN Competencies)
- Theoretical knowledge (CRN/NIHR webinars as well as local inductions)
- Academic programmes (e.g.DMU, UoL)
- Management & Leadership Programmes (UHL, external partners)

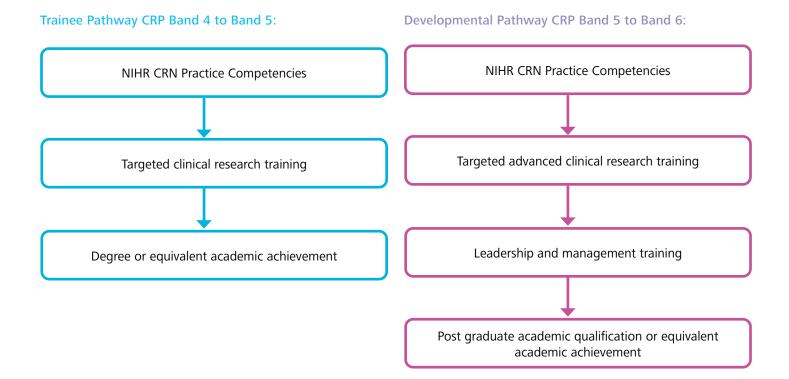
We will be offering development and career progression for all CRP posts including Trainee CRP posts:

- 1. Standard JD/Person Specification (PS) for the level of entry/banding (no additional requirements for structured training/ academic development). Opportunities for enhancing knowledge and expertise will be available and discussed with line managers.
- 2. Trainee Role JD/PS including a structured training programme which will lead to promotion. This will be based on a development programme which will follow a structured approach to learning as an addition to the achievement of advanced competencies. The programme will last for a minimum of 2 years to a maximum of 5 years when the employee will need to submit evidence of development within the role.

Requirement for the authorization of developmental/trainee roles:

- The research area will need to guarantee financial support.
- Final authorization sits with the vacancy panel.

The following pathways will be available and candidates will be expected to complete the course of studies/practice in 3 to 5 years from appointment.



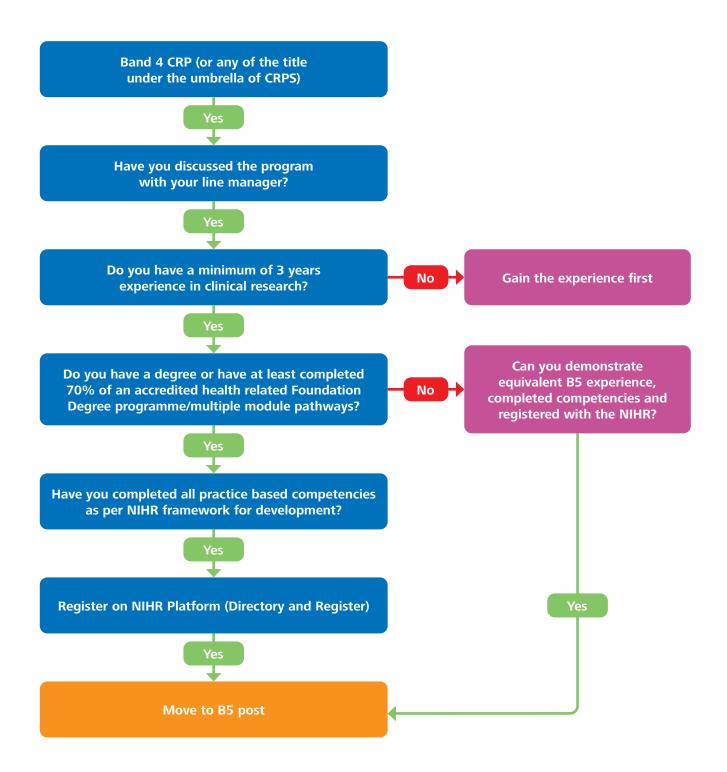
Support available

- Your line manager
- Head of Research (N&M and AHPs)
- NIHR and AHCS
- CRP Website with resources and guidance (to add link)
- CRP Engagement leads and CRP Champions
- 0000 Registered CRPs supporting their non-registered colleagues

Conclusion and impact for the future

Benefits to UHL and the wider health care system





FAQs

- Q How will CRPs be selected for training/development progarmmes?
- A Managers at local level will decide how to progress/who to put forward during appraisals (6 months review/annual review)
- Q What is the capacity and how many CRPs will be selected for development programmes?
- A Managers at local level will decide how to progress/who to put forward during appraisals (6 months review/annual review)
- Q Who will provide the training, possibly to degree level?
- A The NIHR is designing a new academic career progression pathways for CRPs. HEIs can also provide relevant courses.
- Q How will the training/development be funded?
- A Training and development can often be financially supported through UHL Education & Training funding streams. Applications via Head of Research (N&M).
- Q Who is going to fund the promotion/career progression to the next banding level?
- A This will need to be discussed and agreed at local level managers should account for this and include in establishment planning.
- Q How to ensure equity across all areas?
- A A. This strategy provides equity of opportunities. Local managers will decide how to manage training and development at local level.

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