NIHR | National Institute for Health Research

Implementing Accredited Registration for Clinical Research Practitioners

DRAFT
Scope of Practice for Clinical Research Practitioners (CRPs)

Version 0.4 | June 2019

FOR CONSULTATION AND FEEDBACK

Developed within a collaborative initiative led by the NIHR Clinical Research Network for delivery in partnership with the Academy for Healthcare Science (AHCS)

A process to implement accredited registration for Clinical Research Practitioners

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Background

A current scope of practice is being described for Clinical Research Practitioners working as members of the research delivery workforce.

Skills for Health attribute the indicative or reference title of Practitioner at Level 5 of the Skills for Health Career Framework[1], which states that "*people at level 5 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*".

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 draft scope of practice is relevant for those eligible to register as a Clinical Research Practitioner with experience as an unregistered or previously registered practitioner.

Clinical Research Practitioners 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, having the authority to make decisions and act in accordance with their professional knowledge base[2], specifically within the context of delivering clinical research. Expectations of Clinical Research Practitioners will differ depending on education, training and experience, particularly with respect to their clinical knowledge and skills. However, according to the clinical context and research delivery setting, all Clinical Research Practitioners have a duty of care to study participants, and when working in a clinical environment, will be expected to provide and monitor care and to liaise with those assessing, planning, implementing and evaluating care.

The draft scope of practice applies to those in the research delivery workforce who are eligible to register as a Clinical Research Practitioner on the basis of their current education and/or experience. Requirements to be evidenced and assessed by the Academy for Healthcare Science in an application to meet Standards of Proficiency will be defined in User Guidance and will include documented assurance of competence with respect to an organisational competency framework that is aligned with the NIHR Integrated Workforce Framework[3]. Assurance must be provided by one or more appropriate supervisors and countersigned by an approved verifier to acknowledge this.

1. Scope of Practice of Clinical Research Practitioners

1.1 This document outlines a draft scope of practice for Clinical Research Practitioners (CRPs) working in the delivery of research in the NHS and other health and social care settings. The CRP role involves direct contact with study participants and the term 'registered Clinical Research Practitioner' refers to eligible practitioners working at autonomous practitioner level, within the context of research delivery, wherever that research occurs. All Clinical Research Practitioners will be expected to monitor and deliver care and be aware of care that is planned and implemented by others.

1.2 The majority of the professional workforce in research delivery is already registered and regulated by a statutory regulatory body, predominantly Clinical Research Nurses and Midwives, who are regulated by the Nursing and Midwifery Council (NMC). Allied Health Professionals, Pharmacists and Healthcare Science Practitioners are also present as regulated professionals, registered with the Health and Care Professions Council (HCPC), the General Pharmaceutical Council and the Academy for Healthcare Science (AHCS) respectively.

Alongside these registered and regulated professionals, Clinical Research Practitioners have entered the research delivery workforce through other routes, predominantly as degree graduates but also as experienced professionals from a variety of backgrounds (e.g. progression through roles in healthcare, clinical research delivery, the life sciences industry or business).

The professional discipline of Clinical Research Practitioner is being proposed for accredited registration and regulation in the UK through the Academy for Healthcare Sciences (AHCS) Register, which is voluntary and accredited by the Professional Standards Authority (PSA). The PSA is an independent body, accountable to the UK Parliament, and promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and accrediting the registration of people working in health and social care.

Clinical Research Practitioners are involved in a range of activities in delivering research, including:

- Seeking ongoing informed consent as a voluntary agreement with research study participants, ensuring their understanding of the research and its risks
- Identification, screening and randomisation of research study participants
- Involvement in patient care, including Investigational Medicinal Product (IMP) storage/supply and clinical sample processing*
- Involvement in clinical research operations, development, regulation and ethics processes
- Ensuring high quality data input at source and its management through a research workflow
- Communicating across boundaries to maintain relationships that secure investment in research across all clinical specialties and care settings

*Expectations of Clinical Research Practitioners will vary with respect to their clinical knowledge and skills. Sampling and processing for diagnostics provided by others and having an understanding of local medicines management sits within the Scope of Practice for Clinical Research Practitioners and will be expected. According to the requirements of the research study protocol and local policy, Clinical Research Practitioners with adequate training and clinical supervision in place may be expected to collect an IMP from pharmacy, ensure safe storage and/or to supply the IMP to the study participant. Referral to supporting clinical services sits outside the Clinical Research Practitioner Scope of Practice.

1.3 In the absence of a professional body, the NIHR Clinical Research Network and AHCS currently hold responsibility for leadership of the emergent Clinical Research Practitioner profession, and are committed to strengthening the contributions within existing and emerging health and social care teams, to design new roles in line with changing service needs, increasing delivery outside the NHS and expansion in delivery of public health research.

For additional context, the National Institute for Health Research (NIHR) supports the delivery of research in the NHS and across health and social care. The Clinical Research Network (CRN) is part of the NIHR, which is funded through the Department of Health and Social Care to improve the health and wealth of the nation by research.

The NIHR CRN Workforce Strategy 2015-20 clearly laid out the need to nurture and develop the clinical research delivery workforce as the speed of change quickens inthe NHS and extends outside the NHS, across a wider research landscape. The Strategy identifies the need to support this workforce in action and plan for recruitment, retention and career development. The NIHR CRN Workforce Strategy is aligned with both the NHS Workforce Strategy[4] and the NHS Long Term Plan, 2019[5].

The Academy for Healthcare Science is similarly committed to values and interests shared by the NIHR CRN, including workforce, training standards, quality of services, scientific knowledge and applied practise and published Good Scientific Practice in 2012[6].

2. Environment and practice context

2.1 The research delivery workforce is a vital resource. Their skills and expertise ensure that patients and the economy benefit from a vibrant research culture as an integral part of health and care for all. The research delivery workforce is expanding and evolving in response to rapid change across the NHS and wider health and care research landscape. Clinical Research Practitioners form a valued and essential part of this workforce.

2.2 The NIHR CRN Integrated Workforce Framework (IWF)[3] provides a consistent and accessible way of describing roles and defines indicative required knowledge and skills, which may be held and/or applied at one of four levels. The IWF points to active learning, legislation and policy relevant to delivery of clinical research in the UK, including Good Clinical Practice (GCP) as the international ethical, scientific and practical standard to which all clinical research is conducted. The IWF was designed as a resource for employers, and others, to use as part of their approach to support their research workforce. The IWF will serve to complement appropriate local competency frameworks and bring forward education and training available and to be developed for Clinical Research Practitioners and other professionals in the research delivery workforce working across the UK.

2.3 An Education, Training and Professional Standards Committee will provide governance and oversight of the education, training, professional development and career progression of Clinical Research Practitioners, as part of the Academy for Healthcare Science Regulatory Framework.

2.4 Professional and legal frameworks define the way in which professions must practice. AHCS registrants are required to meet the Professional Standards Authority's high standards in governance, standard-setting, education and training, management of the register, complaints handling and information; assuring the public and employers.

The operation and governance of the Academy's Register is overseen by the AHCS Registration Council, which is independently chaired and operates at arms-length from the Academy. The core objective of the Council is to protect the public by mitigating the risks posed to patients and the public by a practitioner workforce that is not regulated by statute.

2.5 Clinical Research Practitioners will be active in the delivery of research across a range of roles, including clinically, and as managers, researchers and educators.

At the present time, Clinical Research Practitioners will be working within a variety of settings, predominantly in the NHS across Primary, Secondary, Tertiary, Mental Health, Community and Social Care; Emergency Departments; Ambulance Services; General Practice and Community Pharmacy.

Clinical Research Practitioners may also deliver research in Independent and Private Health Care Services; Higher Education; Research Establishments and other Public Health and Social Care research delivery environments, including Schools, Prisons, Workplaces, Hubs and Venues. It is anticipated that as the Department of Health and Social Care remit of delivery extends to wider public health and social care research contexts and environments, the range of settings where Clinical Research Practitioners will be working will continue to grow.

2.6 The Clinical Research Practitioner profession needs innovators and role models to take the profession forward. They will be drawn from across the occupational roles, particularly from those in advanced positions and visible as leaders, managers, educators and researchers.

3. Defining individual scope of practice

3.1 Within the roles and sectors described above, a registered Clinical Research Practitioner can develop his or her own scope of practice as he or she determines, provided that he or she is adequately educated and trained and competent to practice. He or she must work ethically and in accordance with the expected code of conduct for their profession, as defined within the Standards of Proficiency for Clinical Research Practitioners.

3.2 In identifying and communicating their individual scope of practice, registered Clinical Research Practitioners must consider the roles and environments in which they work and ensure that they commit to ongoing professional development to continue to meet the Standards of Proficiency for their registration. They must be educated and competent to operate in their specific roles, know the limitations of this and the delivery environment. They must also adhere to the requirements set for supervision in training and know the consequences of poor practice.

3.3 In making decisions about what is included in their individual scope of practice, registered Clinical Research Practitioners must be personally and professionally accountable for all actions, omissions and behaviour and be aware of what is and is not appropriate to delegate. The individual will therefore need to be able to justify any decisions taken within their scope of practice, be able to recognise any deficiencies they may have and take appropriate action to rectify them.

3.4 An individual's scope of practice develops over time. This requires the individual to manage this process to ensure that their knowledge and skills are appropriate to the changes emerging in a rapidly advancing landscape for both health and social care, as well as research. Developments in an individual’s scope of practice need reflect best practice and enhance patient care.

Individual Clinical Research Practitioners must continuously consider what is required within their individual scope of practice and seek to develop and maintain their abilities, to recognise the limits of their competence and to always practice within these. The individual must monitor their practice and the protocols they are working within, using evidence from audit findings and relevant research to develop best practice.

4. Professional indemnity

4.1 Currently, the majority of Clinical Research Practitioners are employed in the NHS or HEIs and/or working within the NHS. Should a mistake happen, NHS indemnity or the employer's liability insurance will be in place to cover staff working within their professional scope of practice. Clinical Research Practitioners should make themselves aware of their employment contract terms, know what their employer's liability insurance policy covers and be clear on what is within their own individual scope of professional practice.

Clinical Research Practitioners are advised to contact their employing organisation's human resources or personnel department for information on what indemnity arrangements are offered and the scope of that cover extended to them by virtue of their employment.

Should a Clinical Research Practitioner be working on a self-employed basis then they will be required to hold their own professional indemnity insurance.

5. Conclusion

5.1 Clinical Research Practitioners will be professionally active in a wide variety of settings according to the clinical context of the research study and the environment for delivery. Increasingly, these may be in settings outside of the NHS.

5.2 Clinical Research Practitioners will be involved interpersonally with those participating in research studies and may be working as managers, researchers and educators.

5.3 Clinical expectations of Clinical Research Practitioners will vary and a clear understanding of individual scope of practice should be reached within research delivery teams.

5.4 The draft scope of practice for Clinical Research Practitioners represents the NIHR and AHCS vision of Clinical Research Practitioners as AHCS registrants, health and care professionals and research delivery experts and is offered for review and feedback from research delivery teams, managers and leaders from across the research delivery system.

6. References

1. Skills for Health Career Framework, available to download at:
http://www.skillsforhealth.org.uk/resources/guidance-documents/163-key-elements-of-the-career-framework

2. Skår R. The meaning of autonomy in nursing practice. J Clin Nurs. 2010 Aug;19 (15-16):2226-34. doi: 10.1111/j.1365-2702.2009.02804.x. Epub 2009 Jun 15

3. The NIHR Integrated Workforce Framework, available to download as a resource at:
https://sites.google.com/nihr.ac.uk/integrated-workforce-framework/home
and available as the IWF digital tool at:
https://iwf.nihr.ac.uk/

4. The NHS Workforce Strategy
https://www.hee.nhs.uk/our-work/workforce-strategy

5. NHS Long Term Plan 2019
https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/

6. Good Scientific Practice, available to download at:
https://www.ahcs.ac.uk/2012/12/12/good-scientific-practice/

Appendix 1

Acknowledgements

The draft scope of practice for Clinical Research Practitioners has been informed by the following current publications:

- NMC Code for Nurses, Midwives and Nursing Associates, 2015;
- HCPC Standards of Conduct, Performance and Ethics, 2019;
- UK Public Health Register Code of Conduct, 2015;
- Standards of Proficiency for Healthcare Science Practitioners, 2016;
- Standards of Proficiency for Nursing Associates, 2018;
- Advisory guidance for nursing associates, 2018;
- The Society of Radiographers Code of Professional Conduct, 2013;

The format of the draft scope of practice for Clinical Research Practitioners models the approach taken for the scope of practice that applies to the professional workforce for diagnostic imaging and radiotherapy, published by the Society of Radiographers in 2013 (ISBN:1-871101-97-2).

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