NIHR Quality Assurance Framework for Clinical Research Practitioners (CRPs)

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1 Introduction

The purpose of the Academy for Healthcare Science's quality assurance function is to maintain high standards of education, training and professional behaviour in the health service, so that patients receive high quality care. It therefore follows that quality assurance (QA) underpins everything it does.

The Academy puts patient interests at the heart of its organisational structure: our independent Regulation Board has both a lay Chair and a lay member majority. This ensures a patient-driven approach to quality assurance. Patient and Public Involvement (PPI) takes into account the views of users, carers and the wider public.

2 Audience

This document is aimed at NHS organisations, health service managers, the research delivery workforce, higher education institutions (HEIs), trade associations, professional bodies and practitioners across health and social care. This Quality Assurance Framework will be published and widely disseminated.

3 The NIHR QA Framework

Creation of a register for Clinical Research Practitioners (CRP) that is underpinned by a QA Framework has been recognised by NIHR and the NHS research community as an effective way to make better use of the skills and potential of staff to meet the expectations of patients and clinical research study participants and ensure the delivery of NHS England's Long-Term Plan (2019) in line with the UK Policy Framework for Health and Social Care research (2018).

The QA Framework ensures that the route to registration remains robust, consistent and fair. See Appendix 1 for a description of the route to registration.

The QA Framework is made up of the following elements:

- Standards on which to base assessment of eligibility to enter and remain on the Register
- Quality assurance of the process to enter the register, including any assessment of applicant skills, knowledge and behaviours
- Enhancing the development of Education and Training

The QA Framework is underpinned by a set of Academy principles (see Appendix 2).

4 Benefits of the QA Framework

- Clinical Research Practitioners able to develop competences and capabilities consistent with the CRP Standards of Proficiency that set out the knowledge, skills, values and behaviours required.
- Reliable assessment processes that support the transferability of competences across employers.
- Clear Academy processes that are recognised and understood by research practitioners, learners, employers, patients, participants, carers and the wider public.

5 CRP Standards of Proficiency

Standards are important in ensuring that Clinical Research Practitioners are fit to practise.

The CRP Standards of Proficiency set out the minimum standard that a person must meet in order to register with the AHCS.

The Standards of Proficiency for CRPs have been shaped in collaboration with CRPs, NIHR Research Delivery Managers, NIHR national Workforce Development Leads and senior leaders in nursing and management of clinical research operations.

The 16 Standards of Proficiency for CRPs are grouped in relation to:

- Professional Responsibility;
- Behaviours, Knowledge and Skills relating to:
    - Clinical Research;
    - Clinical Context; and
    - Leadership.

They align with standards published for Nurses, Midwives and Nursing Associates, Allied Health Professionals and Healthcare Science Practitioners as well as the NIHR Integrated Workforce Framework for clinical research delivery.

6 CRP Scope of Practice

A scope of practice is described for Clinical Research Practitioners working as members of the research delivery workforce in clinical environments and other health and social care settings. This scope of practice is referred to within the CRP Standards of Proficiency.

7 Registration, Regulation and Fitness to Practise

The 16 Standards of Proficiency for CRPs are required in order to make judgements on individuals for entry to and removal from the Academy's NIHR CRP register. The standards set out the knowledge and skills required by a professional as well as expectations for professional practice.

Regulation exists to protect the public against the risk of poor practice. It works by setting agreed standards of practice and competence, and registering those individuals who meet those standards and who have been assessed as competent to practise.

Registration of professionals helps to protect patients and individuals participating in clinical research and is increasingly viewed as essential by employers, providers, commissioners and patients themselves and can be viewed as a positive contribution to meeting expectations of the Care Quality Commission (CQC) Well Led Framework. Through registration, an individual shows commitment to upholding high professional standards and to keeping their knowledge, skills and experience up-to-date through ongoing professional development. If individuals fail to uphold standards or show that they are fit to practise, their circumstances will be reviewed and they may have their Registration status restricted or removed.

The Academy's NIHR CRP Register will be accredited by the Professional Standards Authority (PSA)*. Commissioned by Health Education England (HEE), the Academy's Register is an important step in achieving our long-term aim of supporting all parts of the healthcare workforce to achieve statutory regulation.

* See here for more information on the PSA's Accredited Register scheme.

8 Quality Assurance of the Registration assessment process

The Academy in partnership with NIHR will undertake regular quality assurance activities to ensure that that the assessment of an individual application to join the NIHR CRP Register is robust, fair and consistently applied.

Activities will include:

- A robust recruitment and training of assessors, including a standardization exercise
- A moderation process
- An annual sample of pre-submission verification of evidence and AHCS assessments and guidance documentation by an external examiner/scrutineer appointed by the Academy in partnership with NIHR An annual review meeting with key stakeholders Preparation of an annual quality review report.

9 The Academy's commitment to driving up the quality of education and training

As part of its Quality Improvement role, the Academy and NIHR's shared commitment will:

- Carry out regular monitoring and sampling against agreed performance indicators to measure progress in achieving quality improvement aims and objectives.
- Value stakeholder feedback evaluation from the service, students / trainees, patients, other participants in clinical and health related research as well as the public. This evaluation will inform decisions on the further targeting of quality assurance activities and on the further development of standards, education and training.
- Share information on best practice with a range of organisations, including NIHR, NHS Employers, NHS England, Health Education England and the Professional Standards Authority. We are all working towards better standards across the board. Feedback provides us with good intelligence on areas that need to be improved. By critically assessing evidence of what works and what does not work, we are able to focus our communications on specific approaches that are most likely to have a positive impact on raising standards.

Appendix 1: Registration Guidance

Registration on the NIHR CRP Register is achieved through the presentation of evidence by Clinical Research Practitioners against the CRP Standards of Proficiency. AHCS-NIHR assessors will review the evidence presented and make a judgement as to whether the applicant has met the Standards and therefore can be granted eligibility to join the Register.

As a minimum, applicants must submit a professional testimonial of their performance as a Clinical Research Practitioner together with evidence to demonstrate:

Practice Knowledge and Experience:

Structured reflections on:

- understanding of their professional accountability and limitations;
- their leadership in advocacy for research and the CRP profession, and;
- two examples of working across professional and organisational boundaries, addressing permissions accordingly in relation to their role.

Documented assurance to confirm:

- their competence with respect to an organisational competency framework that is aligned with the NIHR Integrated Workforce Framework;
- their communication style, observed and noted to confirm that this is adequate and appropriate, including when taking informed consent where relevant;
- their practice knowledge and their hours and context of practice experience, discussed as part of a development conversation with a statutory registered healthcare professional, and;

Certified Training:

- Good Clinical Practice (GCP) – Transcelerate-accredited
- Statutory and Mandatory Training – all subjects of the UK Core Skills Training Framework (v1.6)

Education:

- (a) An undergraduate degree[1] or Level 6/7 apprenticeship from a higher education provider recognised by the appropriate regulatory body

  OR

- (b) Highest academic achievement from a recognized education provider, a summary of experience at an appropriate level and Curriculum Vitae[2] **Confirmation:**
  Confirmation of the evidence provided must be assured by the applicant's line manager and a named individual who is trained and recognised as part of the NIHR verifier cohort .

[1] In the UK the Higher Education Institution must be on the Office for Students list of recognised providers. Where the degree has been awarded by an overseas provider a NARIC certificate indicating comparability is required

[2] Where education is below undergraduate degree level and a CV is submitted together with all other evidence, this will be assessed for equivalence to meet the Standards of Proficiency. Additional evidence may be required. This route to registration is likely to close once registration for CRPs has been in place for 2 years.

Appendix 2: Academy Principles in the application of Quality Assurance processes

Principle	Standards	Quality Assurance processes
Proportionality ('Right touch')	The burden created to comply with standards should be proportionate to the risks presented. Standards are normally expressed as outcome statements, to allow a diversity of approaches to meeting them. As far as possible, standards will be applicable across the disciplines and roles of the healthcare and research workforce.	It is a requirement that organisations and individuals undertake activities that help to mitigate risk. As far as possible, processes must call on evidence that already exists.
Accountability	In producing and revising standards, there will always be appropriate public consultation. Standards will be reviewed periodically to ensure that they remain fit for purpose.	The Academy will be accountable to the Professional Standards Authority (PSA).
Consistency	Adherence to standards must be measurable. As far as possible, standards will be consistent with other standards relevant to healthcare science.	It is a requirement that individuals involved in QA are trained and developed, to ensure consistency. QA decisions will be independent of both education commissioners and providers and will be evidence-based.
Transparency	The process for producing standards will be transparent, with clear points of consultation and the inclusion of organisational, professional and lay views. The purpose of standards will be transparent and will be available on the Academy's website.	QA processes will be transparent to all organisations and the individuals who must use them, including members of the public. Processes include observations of the assessment provisions of education providers. The outcomes from QA activities will be publicly accessible via the Academy web site.
Targeting	Standards are targeted at areas of risk. When standards are reviewed, the creation of new standards or revisions to existing standards will be based in part on the evidence of risk.	QA processes will identify risk and prioritise areas of high risk over areas of low risk. Where other bodies operate QA processes in the same setting, targeting will be used to prevent the duplication of evidence collection.
Agility	Standards will not inhibit the development of a profession or service, provided all risks have been reasonably mitigated. Standards will be reviewed periodically to mitigate new and emerging risks and amended where evidence suggests that existing standards require it or removed if they lack continued relevance.	Wherever possible QA will be pro-active and with an emphasis on risk prevention.