

Accredited Registers

Notification of Change

The Academy for Healthcare Science

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About the Academy for Healthcare Science

The Academy for Healthcare Science (the Academy) registers:

- Healthcare Science Practitioners working in many occupations
- Higher Specialist Scientists
- Clinical Physiologists
- Medical Illustrators
- Genetic Counsellors

The Academy also holds a credentialing register for the Life Science Industry (LSI), admitting company representatives who trade with and provide services to the National Health Service (NHS).

The Academy's work includes:

- Setting and maintaining standards of practise and conduct
- Maintaining a register of qualified professionals
- Assuring the quality of education and training
- Requiring registrants to keep up their skills up to date through continuing professional development
- Handling complaints and concerns raised about registrants and issuing sanctions where appropriate

The Academy was first accredited on 18 December 2014. As of October 2019, there were 1,700 registrants on the Academy's registers.

Background

The Professional Standards Authority accredits registers of people working in a variety of health and social care occupations not regulated by law. To be accredited, organisations holding such registers must prove that they meet our demanding [Standards for Accredited Registers](#) (the Standards). Accreditation is reviewed every twelve months.

Once accreditation has been granted, significant changes to an Accredited Register need to be assessed by the Authority to ensure ongoing compliance with the Accreditation Standards. These are submitted to the Authority as a notification of change.

Changes can be approved by a Moderator in cases where compliance with the Standards are not affected by the change. A Moderator can issue Recommendations and note Achievements.

Where concerns do exist, or information is not clear, a targeted review will be initiated by a Moderator. The outcome of this review is assessed by an Accreditation Panel, who can decide to approve the change or approve the change with conditions. Panels may also issue Recommendations and note Achievements.

- **Condition** – Changes that must be made within a specified timeframe to maintain accreditation
- **Recommendation** – Actions that would improve practice and benefit the operation of the register, but do not need to be completed for compliance with the Standards to be maintained. Implementation of recommendations will be reviewed at annual renewal
- **Achievement** – Areas where a register has demonstrated a positive impact on one of the four pillars of the programme; protection, choice, confidence and quality.

Notification of Change

The [Academy](#) is an overarching body for the healthcare science profession, working alongside specialist professional bodies and societies to promote healthcare science and the healthcare science profession. The Academy operates Accredited Registers for healthcare science practitioners, higher specialist scientists, medical illustrators, clinical physiologists and a credentialing register for the life sciences industry.

The Academy proposed to add Clinical Research Practitioners to its register. The Academy described Clinical Research Practitioners ‘as an umbrella title for a family of roles in research delivery that have a patient-facing element and where the post-holder is not currently registered to a healthcare profession. The post-holder will often be a degree graduate, though not always, who may be working to deliver research in a variety of different settings, including community and social care environments and as part of public health initiatives.’

The Academy noted that adding this group to its register will help ensure that ‘their skills and expertise can be assured to patients and the public, employers and partners, including the Life Sciences Industry. In addition, the skills and expertise of individual Clinical Research Practitioners can be better valued and developed and the professional identity of Clinical Research Practitioners as a group can become recognised within the delivery of research and the health and social care workforce.’

The Academy developed *Standards of Proficiency* setting out the minimum standard that a person must meet in order to join the register. These were developed following consultation with Clinical Research Practitioners, National Institute for Health Research (NIHR) Research Delivery Managers, NIHR national Workforce Development Leads and senior leaders in nursing and management of clinical research operations. There are 16 Standards consistent with the Academy’s existing standards for other occupations its registers. Clinical Research Practitioners would be subject to the same quality assurance and registration standards as other existing registrants. Complaints against Clinical Research Practitioners would be heard by panels set up by the Clinical Research Practitioners Registration Council with any appeals being heard by the Academy’s Regulation Board.

The Academy has advised that its governance and administrative structure would not need to be significantly changed to manage the new occupation. The Chair of the Clinical Research Practitioner Registration Council will sit on the Academy’s Regulation Board and also be the link between NIHR and the CRP Registration Council.

Outcome

The Authority decided that the changes would not negatively impact on the Academy's compliance with the Accreditation Standards so approved the change.

The change was approved by a Moderator following a review of evidence gathered by the Accreditation team and supplied by the Academy.

No Conditions or Recommendations were issued.

The following report provides detail supporting the outcome.

Assessment against the Standards for Accredited Registers

Standard 1: the organisation holds a voluntary register of people in health and/or social care occupations

- 1.1 The Academy proposed to add the occupation and title of 'Clinical Research Practitioner (CRP)' to its registers. CRP work involves monitoring and delivering care to medical research study participants. The Academy described CRP as 'an umbrella title for a family of roles in research delivery that have a patient-facing element and where the post-holder is not currently registered to a healthcare profession.'
- 1.2 The Academy provided its *Scope of Practice for Clinical Research Practitioners* listing the range of activities undertaken by CRPs 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
- 1.3 The Scope highlighted that while the majority of the workforce in research delivery are healthcare professionals under statutory regulation (with the Nursing and Midwifery Council (NMC), Health and Care Professions Council (HCPC) or the General Pharmaceutical Council (GPhC)) unregulated CRPs had entered the workforce through other routes, as degree graduates and as experienced professionals from other backgrounds.
- 1.4 Such CRPs work within a variety of settings:

'in the NHS across Primary, Secondary, Tertiary, Mental Health, Community and Social Care; Emergency Departments; Ambulance Services; General Practice and Community Pharmacy. CRPs 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.'

- 1.5 The Academy advised that together they form part of the research delivery workforce which is 'evolving in response to rapid change across the NHS and wider health and care research landscape'.
- 1.6 The Academy advised that prior to its application an unaccredited Directory had been published on its website with 500 CRPs.
- 1.7 The Academy confirmed it can register CRPs who are also registered with statutory regulators such as the NMC or HCPC, that also met the Academy's standards.
- 1.8 The Authority decided that Clinical Research Practitioners met the definition for working in a health care occupation set out in the National Health Service Reform and Health Care Professions Act 2002, section 25E (8) - 'Health care' includes: all forms of health care for individuals, whether relating to physical or mental health; and procedures that are similar to forms of medical or surgical care but are not provided in connection with a medical condition.'
- 1.9 The Authority considered that it may be possible that some registrants may work in academic settings or otherwise not be involved in clinical work or the immediate treatment of patients / service users. However as with other occupations on Accredited Registers (for example public health practitioners) they would have a role in provision of healthcare, health improvement, and health protection.
- 1.10 The Authority found that compliance with this Standard was not affected by the change.

Standard 2: the organisation demonstrates that it is committed to protecting the public and promoting public confidence in the occupation it registers

- 2.1 The Academy advised that CRPs will work to 'deliver research in a variety of different settings, including community and social care environments and as part of public health initiatives.' CRPs may have direct contact with patients and service users.
- 2.2 The Academy demonstrated commitment to protecting the public and promoting public confidence in the CRP occupation through development of its Standards of Proficiency, Scope of Practice and other requirements of registration for CRPs. The Academy and NIHR intended that accreditation of this register demonstrate that CRPs have met those standards and provide assurance to patients entering into clinical studies.
- 2.3 The CRP standards are modelled from existing Academy standards, which mitigate the risk of harm to service users and the public by practitioners across each of its register categories. The standards include requirements to work within defined scopes of practice, and to work effectively within multidisciplinary teams.
- 2.4 The Academy also intended that accreditation highlight the skills and expertise held by CRPs to patients and the public, employers, and partners such as the Life Sciences Industry. This would assist development of the professional identity and recognition of unregulated CRPs within the delivery of research in the health and social care workforce.

- 2.5 The Academy's most recent Annual Review application set out its awareness of matters relating to safeguarding. This included all registrants' requirements to, at minimum, provide evidence of a basic, or higher, Disclosure and Barring Service (DBS) check dated within the three years prior to application. The Academy advised it was developing universal competence standards for safeguarding, and advised it was reviewing guidance which would refer to 'Adhering to legislation and policies in situations when working with children or vulnerable adults'.
- 2.6 The Authority found that compliance with this Standard was not affected by the change.

Standard 3: risk management

- 3.1 The Authority noted the Scope of Practice highlighted that 'the CRP role involves direct contact with study participants' and that registrants may work autonomously 'within the context of research delivery, wherever that research occurs'. The Academy advised that it and the NIHR 'have considered the respective risks and benefits to service users and the public and, in particular whether there are there any risks to safety or welfare.'
- 3.2 CRP registrants will be subject to the Academy's existing risk management practices and practices specific to this occupation. The Scope of Practice highlighted standards set by the Academy to mitigate risk of harm to patients / service users by CRPs through, for example:
- the need to obtain informed consent.
 - CRPs will have adequate training and supervision to supply Investigational Medicinal Products (IMP) to study participants.
- 3.3 The Academy's Standards of Proficiency listed requirements for registrants that would assist in mitigation of occupation specific risks, for example: 'Apply practice in line with Good Clinical Practice (GCP) as the international ethical, scientific and practical standard to which all clinical research is conducted.'
- 3.4 The Academy advised that its risk register for CRPs would be reviewed at Registration Council Meetings and also scrutinised by the Regulation Board. The Academy also advised that it would maintain 'active liaison and information sharing with leaders and managers who support CRPs' at local level'. The Authority would review updates to its risk register at future annual reviews of accreditation.
- 'The risk matrix for the CRP Register will be reviewed at Registration Council Meetings and also scrutinised by the Regulation Board. In order to ensure that identified risks and mitigations are relevant to and informed by practice, there will be active liaison and information sharing with leaders and managers who support CRPs' at local level. This will include the insights and evaluation of risks that will be shared by a national panel of local verifiers and a community of Workforce Development leads who have oversight of the research delivery workforce at local level.'
- 3.5 The Authority found that compliance with this Standard was not affected by the change.

Standard 4: the organisation demonstrates that it has sufficient finance to enable it to fulfil its voluntary register functions effectively including setting standards, education, registration, complaints and removal from the register

- 4.1 The Academy confirmed that fees paid by CRP registrants will be managed in the same way as other Academy registrant categories. Registrants pay £30 per annum by direct debit.
- 4.2 The Authority noted that the inclusion of this register category could assist sustainability.
- 4.3 The Authority found that compliance with this Standard was not affected by the change.

Standard 5: the organisation demonstrates that it has the capacity to inspire confidence in its ability to manage the register effectively

- 5.1 The Authority noted that the Academy had worked closely with the NIHR as an appropriate expert body when preparing for the inclusion of CRPs on its register.
- 5.2 The Authority found that compliance with this Standard was not affected by the change.

Standard 6: the organisation demonstrates that there is a defined knowledge base underpinning the health and social care occupations covered by its register or, alternatively, how it is actively developing one. The organisation makes the defined knowledge base or its development explicit to the public

- 6.1 The knowledge base for CRPs has been defined within its Scope of Practice, developed by the NIHR Clinical Research Network in collaboration with the Academy. The Scope, updated following an open consultation, was issued in December 2019.
- 6.2 The Academy makes its defined knowledge base for existing register categories explicit to the public. For example, the curricula for Practitioner Training Programme (PTP) courses undertaken by registered Healthcare Scientists are linked to from the Academy website and hosted on the National School for Healthcare Science website. The Academy's *Good Scientific Practice* and specialist standards of proficiency are published on the Register Standards and Rules section of the Academy website.
- 6.3 The Authority found that compliance with this Standard was not affected by the change.

Standard 7: governance

- 7.1 The Academy advised that the CRP register will sit within the Academy's existing regulatory framework. The 'CRP Registration Council', (similar to the Healthcare Scientist (HCS) and Life Sciences Industry (LSI) Registration Councils) will form part of the AHCS Regulation Framework and report to the Regulation Board.
- 7.2 The CRP Registration Council Chair will attend the Academy's Regulation Board, in the same way that all Council Chairs attend and report. The

Academy highlighted that the Board has a lay chair and majority lay-membership.

- 7.3 Information about CRPs is currently presented on the non-Accredited directory published on the Academy website. A link is provided to the accessible directory (to be migrated to the main register if accredited). A link is also provided to the NIHR website which provides information about the work of CRPs and information on applying to join the directory. If the Notification of Change was approved the details of CRP registrant would be published on the public register on the Academy's website.
- 7.4 The Academy advised its website was being upgraded to provide information about the role of CRPs, its knowledge base, education requirements, and links to other sites, including to relevant materials and information on the NIHR web site. The Authority will review this information in the course of its regular assessments.
- 7.5 The Academy had advised that the 'AHCS and NIHR will share information to the extent allowed by the General Data Protection Regulations (GDPR) and as set out in the AHCS Privacy Notice.' The Academy confirmed it would be able to perform all register functions for CRPs as with all other categories, with no limitations. The Academy advised that if appropriate, anonymised data will be shared between the Academy and NIHR to support workforce planning for CRPs, and will be overseen by the Academy's Regulation Board, as for all other register categories.
- 7.6 The Authority found that compliance with this Standard was not affected by the change.

Standard 8: setting standards for registrants

- 8.1 Standards for the CRP workforce are set out in the Academy's Standards of Proficiency (SOPs) which were mapped from its existing SOPs. The CRP SOPs set out the minimum standards that a person must meet and maintain in order to join the Academy's register.
- 8.2 The Academy's QA Framework states that
- '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.'
- 8.3 The Academy advised that annual sampling of evidence will be undertaken to assure that assessment of CRP applications to the register is 'robust, fair and consistently applied.'

- 8.4 The Scope of Practice highlighted that CRPs must be covered by relevant indemnity protection whether through their employer or individually held.
- 8.5 The Authority found that compliance with this Standard was not affected by the change.

Standard 9: education and training

- 9.1 Education and training requirements for the new register category are set out in the *NIHR Quality Assurance Framework for Clinical Research Practitioners (CRPs)*. 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'
- 9.2 The QA Framework states that the minimum level of education required for entry to the register is:
- 'An undergraduate degree or Level 6/7 apprenticeship from a higher education provider recognised by the appropriate regulatory body, or
 - Highest academic achievement from a recognized education provider, a summary of experience at an appropriate level and Curriculum Vitae'. (to be assessed for equivalence)
- 9.3 The QA Framework states that the Academy will help drive up quality of education and training by, for example, 'monitoring against quality improvement aims and objectives', and receiving 'stakeholder feedback evaluation from the service, students / trainees, patients, other participants in clinical and health related research as well as the public'. The Academy will 'Share information on best practice with a range of organisations, including NIHR, NHS Employers, NHS England, Health Education England and the Professional Standards Authority'.
- 9.4 The Authority found that compliance with this Standard was not affected by the change.

Standard 10: management of the register

- 10.1 The Academy advised that CRP registrants would be listed on its searchable register alongside its other occupations. CRP registrants will have their specialities published under that section of the register.
- 10.2 The Academy will assure that only those who meet its standards may join the register through assessment of evidence presented by applicants against the SOPs, which will be reviewed by AHCS-NIHR assessors.
- 10.3 Applicants must submit evidence demonstrating they meet the education requirements (as set out in Standard 9), requirements for 'Practice Knowledge and Experience' (through, for example, structured reflections demonstrating understanding of professional accountability and limitations) and also 'Certified Training'

- 10.4 The Academy confirmed that its Regulation Board will consider appeals against decisions by the Registrar about a person's admission to or removal from the register (including fitness to practise decisions).
- 10.5 CRP registrants will be held accountable to the *AHCS Standards for Continuing Professional Development*. The Academy conducts an annual sample audit of registrants requiring proof of compliance with the CPD standards over the previous two years.
- 10.6 The Academy confirmed that CRPs who are presently listed on the public directory will undergo full assessment to assure they meet the defined CRP Standards of Proficiency and other criteria as for all Academy registers. There would be no 'grandfathering' of practitioners to the register.
- 10.7 The CRP Directory will continue to act as a community space to connect and support those working at different levels of practice and provide a source of information and support for those working towards registration.
- 10.8 The Authority found that compliance with this Standard was not affected by the change.

Standard 11: complaints and concerns handling

- 11.1 The Academy advised that 'Fitness to Practise procedures for CRP registrants will be carried out under the auspices of the NIHR CRP Registration Council with all appeals and unresolved FTP cases being handled by the AHCS Regulation Board.'
- 11.2 The Academy confirmed that complaints processes set out in the *Healthcare Science (HCS) Practitioner Registration Council Fitness to Practise Rules 2020* will apply, with the substitution of the NIHR CRP Registration Council for (HCS) Practitioner Registration Council. The Academy also confirmed that the current Academy process and guidance for raising a concern about a registrant will apply to the CRP register.
- 11.3 The Authority found that compliance with this Standard was not affected by the change.

Share your experience

- 12.1 The Accreditation team did not receive any responses from the share your experience process.

Impact assessment

- 13.1 The Panel noted and took account of the impact of its decision to approve the change. The Authority noted that raising standards for CRPs should help ensure research is well conducted for the benefit of the public.

Equality duty under the Equality Act 2010

- 14.1 The Authority had regard to its duty under the Equality Act 2010 when considering the notification of change.