Standards of Proficiency for Clinical Research Practitioners (CRPs)

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Document Control

Versions:

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1.0	28.04.20	Janice Paterson	As submitted to and reviewed by the Professional Standards Authority, April 2020
1.1	22.03.21	Janice Paterson	Cover and Document control panel refreshed at open launch of the CRP Register

Professional Responsibility - Standard 1

Practise as an autonomous and accountable professional, exercising your own judgement within the boundaries of your role.

To achieve this as a Clinical Research Practitioner you must:

1.1 Practise according to the principles and values of both the NHS Constitution and the UK policy framework for health and social care research, observing your responsibilities to patients, service users and the public in all settings where you may be working to deliver research.

1.2 Draw on appropriate skills and knowledge in order to make professional judgements according to your scope of clinical research practice.

1.3 Assess a situation, determine the nature and severity of any problem and call upon the required knowledge and experience to deal with it through appropriate escalation.

1.4 Understand and respect the roles and responsibilities within research delivery teams, delegation of duties and how your own role fits within the team in relation to your scope of practice, knowing your own limitations and the consequences of poor practice.

Professional Responsibility - Standard 2

Practise safely and effectively within your scope of professional competence

To achieve this as a Clinical Research Practitioner you must:

2.1 Work within your agreed scope of clinical and health related research practice, which may include clinical skills and procedures, for lawful and ethical, safe and effective delivery of research in clinical environments and other health and social care research settings.

2.2 Know the limits of your own competence and when to seek advice or refer to another professional through recognised escalation processes within the team and/or organisation.

2.3 Effectively supervise and delegate responsibility where appropriate and according to your role.

2.4 Ensure and enable appropriate training and development of self and others, according to the responsibilities of your role.

Professional Responsibility - Standard 3

Maintain fitness to practice and behaviours that support professionalism

To achieve this as a Clinical Research Practitioner you must:

3.1 Act to maintain and protect your own health and wellbeing.

3.2 Maintain high standards of personal, professional and business conduct including participating in annual appraisal or personal development review.

3.3 Reflect critically and continuously on performance or situations and actively seek feedback from colleagues and research study participants.

3.4 Deal with differences of opinion with colleagues through discussion, respecting their views and opinions and behaving in a professional way at all times, and by escalation as required.

Professional Responsibility - Standard 4

Understand the impact of culture, equality and diversity on clinical research study participants and the need to safeguard and act in a non-discriminatory manner

To achieve this as a Clinical Research Practitioner you must:

4.1 Adapt practice to meet the diverse needs of research study participants and their families to:

- safeguard the participant's individual physical, psychological, religious and cultural needs and preferences in line with the clinical care baseline defined;
- respect and uphold the rights, dignity, values and autonomy of research study participants, including your role and their role according to the study design;
- recognise and address issues of inequality in relation to research provision for all communities.

4.2 Modify communication following assessment of study participants to act as an advocate and take account of:

- age, gender, diversity;
- impairment of the senses - mental and physical;
- the circumstances and clinical context in which research study participants may be approached or consent to be involved;
- values, concerns, ideas, expectations, needs and feelings, in any health condition and according to social or cultural context, including any need for a qualified interpreter;

Professional Responsibility - Standard 5

Communicate clearly

To achieve this as a Clinical Research Practitioner you must:

5.1 Communicate clearly and effectively in English, and/or Welsh, checking that you are understood

5.2 Demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to research study participants, their relatives and carers and your colleagues.

5.3 Take reasonable steps to meet people's language and communication needs, providing assistance and/or adjusting your language or communication methods where required.

Professional Responsibility - Standard 6

Practise within the legal and ethical boundaries of your profession as a Clinical Research Practitioner.

To achieve this as a Clinical Research Practitioner you must:

6.1 Demonstrate your understanding of:

- the scientific and ethical principles which inform the practice of health and social care research;
- the standards of proficiency, which include reference to the conduct and continuing professional development that will be expected of you by the Academy for Healthcare Science;
- the need for others to plan care, your role in monitoring and delivering care and the boundaries of this, according to your role and individual scope of practice.

6.2 Meet the requirements of the current legislation and policy applicable to your work, including uptake of your organisational statutory and mandatory training.

Behaviours, Knowledge and Skills - Clinical Research - Standard 7

Apply practice in line with Good Clinical Practice (GCP) as the international ethical, scientific and practical standard to which all clinical research is conducted.

To achieve this as a Clinical Research Practitioner you must:

7.1 Demonstrate your understanding of the UK Policy Framework for Health and Social Care Research to comply with GCP in order to provide public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable.

7.2 Demonstrate your application of GCP and understand the processes in place for incident reporting, safety reporting and pharmacovigilance in accordance with GCP and UK Health Research Authority processes, according to your role.

7.3 Demonstrate your understanding of the current structure and function of Health and Social Care services in the UK and the research policy environment of the NIHR, Charities, other funding bodies and the Life Sciences Industry.

7.4 Demonstrate your understanding of what you have perceived to be right for the research study participant, taking into account mental capacity and the needs of children and vulnerable adults.

7.5 Select and use methods and procedures appropriate to the research study protocol to identify, recruit, screen and randomise participants, according to your role and in line with local policies and procedures, including:

- clinical and practical skills for essentials measurements, data generation and analysis;
- assessment and evaluation of methods and procedures;
- clinical sampling, processing and/or diagnostic investigations as required.

Behaviours, Knowledge and Skills - Clinical Research - Standard 8

Describe and implement clinical research study design

To achieve this as a Clinical Research Practitioner you must:

8.1 Demonstrate your understanding of the design and development of different types of clinical and health related research studies

8.2 Demonstrate that you are able to:

- contribute to appraisal of evidence gathered in the context of delivering a research study;
- engage research study participants in the process of seeking informed consent;
- engage with colleagues in relation to research study design and implementation and evaluation;
- contribute to reporting and dissemination of results, irrespective of study outcome.

Behaviours, Knowledge and Skills - Clinical Research - Standard 9

Understand the need to establish and maintain a safe environment in which research care is delivered in all settings that may apply

To achieve this as a Clinical Research Practitioner you must:

9.1 Take reasonable care of health and safety at work for yourself, team members and others, and cooperate with employers to ensure compliance with health and safety policy and procedures as dictated by the research delivery setting.

9.2 Demonstrate your understanding of your role, and according to your role, understand the workflow to deliver clinical research that meets the workload intensity, including being able to:-

- contribute to appropriate project plans and strategies, including writing of standard operating procedures and dedicated project management documentation;
- adhere to set timescales and budgets;
- monitor and review the ongoing effectiveness of planned activity, modifying as and when necessary to prioritise appropriately in a changing environment.

9.3 Identify and manage sources of risk in the workplace, including meetings with research study participants, clinical sampling and waste disposal.

9.4 Use necessary equipment, technology and software proficiently in accordance with standard operating procedures and guidelines.

Behaviours, Knowledge and Skills - Clinical Research - Standard 10

Understand the overarching quality assurance processes within clinical research study and site management that protect participant confidentiality rights and data integrity

To achieve this as a Clinical Research Practitioner you must:

10.1 Understand the Study Protocols and relevant Standard Operating Procedures that apply to a given clinical research study and within an organisation, including information governance, data management and application of these.

10.2 Keep accurate, comprehensive and comprehensible records for a clinical research study according to Good Clinical Practice (GCP) standards and local policy guidance relating to:

- source data within patient records;
- logs for delegation of duties;
- responsibilities and training;
- reference documents within the study site file.

Behaviours, Knowledge and Skills - Clinical Context - Standard 11

Understand the key concepts of the knowledge base relevant to Clinical Research Delivery.

To achieve this as a Clinical Research Practitioner you must:

11.1 Demonstrate your understanding of basic physiology, including vital signs and physiological parameters, psychological wellbeing and mental health parameters, including having the skills to recognise the deteriorating patient and acting appropriately in response as part of your duty of care .

11.2 Understand the value of research and its contribution to evidence based care, including being able to articulate your own contribution.

Behaviours, Knowledge and Skills - Clinical Context - Standard 12

Understand the importance of and be able to maintain confidentiality and meet the need for transparency in the delivery of clinical research as an integrated part of healthcare.

To achieve this as a Clinical Research Practitioner you must:

12.1 Demonstrate appropriate sharing of information with research study participants, carers, colleagues and other services to support the quality of research care in line with published guidance and legal requirements, including General Data Protection Regulations (GDPR) in relation to data protection and participant confidentiality.

12.2 Understand that the requirements of confidentiality and informed consent extend to (for example) test results, recordings, digital images and illustrations.

12.3 Understand that your conduct should at all times justify the trust in your profession from research study participants, carers, colleagues and the public.

Behaviours, Knowledge and Skills - Clinical Context - Standard 13

Understand the importance of and act in response to variables within the context of and environment for delivery of clinical research as an integrated part of health and social care

To achieve this as a Clinical Research Practitioner you must:

13.1 Demonstrate that you understand the variables that will apply in a variety of different research delivery settings, including assessing the limitations related to:

- frequency and familiarity of your exposure to the activity and the environment;
- complexity of study participant population and the research delivery environment;
- predictability of the situation and availability of access to someone with skills that are complementary and/or more advanced to your own;
- challenges that may compromise the research delivery environment and signposting as appropriate;
- risks of lone working and organisational policies on this.

13.2 Take appropriate measures for infection prevention and control, including use, cleaning and maintenance of equipment and ensuring usability of consumables e.g. expiry dates.

Behaviours, Knowledge and Skills - Clinical Context - Standard 14

Contribute to clinical and health related research through your role as an integral part of high quality health and social care

14.1 Understand the importance of a commitment to improving healthcare through design and conduct of excellent clinical and health related research that ensures safety, promotes quality and is undertaken with respect and compassion.

14.2 Understand the need to take responsibility not only for the care that you may personally provide to research study participants, patients, and the public, but also for your wider contribution to the aims of your team and the healthcare system as a whole.

14.3 Understand your own accountability and the accountability carried by clinical colleagues with respect to your duties in monitoring and delivering care.

14.4 Actively contribute to sustainably improving best practice and innovation in research delivery and service improvement, including clinical care.

Behaviours, Knowledge and Skills - Leadership - Standard 15

Understand the importance of following principles within a consistent approach to leadership

To achieve this as a Clinical Research Practitioner you must:

15.1 Demonstrate your awareness of the themes of the Developing People, Improving Care Framework, the dimensions of the Healthcare Leadership Model and the standards of the NHS Leadership Framework and apply these according to your role.

15.2 Demonstrate understanding of your own role and enter into coaching and mentoring relationships to actively model and develop your leadership style.

Behaviours, Knowledge and Skills - Leadership - Standard 16

Understand the importance of the leadership responsibility in service delivery, management and improvement and contributing to the knowledge base of the profession

To achieve this as a Clinical Research Practitioner you must:

16.1 Demonstrate your ability to lead confidently across networks and have a deep understanding of the research delivery system and research being part of core business in health and social care.

16.2 Demonstrate a collaborative and cooperative approach that contributes to the culture of research delivery as a shared endeavour.

16.3 Demonstrate credibility, confidence and resilience, and the ability to lead in times of rapid change

16.4 Demonstrate leadership competencies where these are required in your role, including:

- people management, staff wellbeing and development;
- inspiring shared purpose and engaging the team.

16.5 Actively participate in activities promoting your profession and its contribution to research including demonstrating your understanding of:

- the potential of digital technologies to transform research delivery and health and social care;
- the impact and benefits of research for the wider health system;
- your own contribution to the knowledge base and articulation of this.