Defining Competencies in Clinical Research: Issues in Clinical Research Education and Training

By Carolynn Thomas Jones, MSPH, RN; Shaunagh Browning, RN, FNP-BC; Barbara Gladson, PT, PhD; Carlton Hornung, PhD, MPH; Barbara G. Lubejko, MS, RN; James Parmentier, PhD; Helen Pidd, RGN, MSc; Honorio Silva, MD; and Stephen Sonstein, PhD, M(ASCP)

Key words: *clinical research, competencies, education, training*

Learning Objectives:

1. Define outcomes-based education.
2. Explain how outcomes-based education provides a framework for executing educational programs in clinical research.
3. Discuss how to develop core competencies for clinical research professionals.
4. List core competencies and domains of practice for physician and nursing groups.
5. Provide appropriate care and counsel for patients and their families.

Professional responsibilities in clinical research have increased substantially in the past decade, in part due to an increasing complexity of clinical protocols combined with the global expansion of pharmaceutical product development which has resulted in a scarcity of appropriately educated and trained personnel in the developing countries. Despite this increase in workload complexity, clinical research professionals continue to report that most of their learning takes place "on the job" and through the accumulation of work experiences.[1-4] As the clinical research enterprise continues to expand, there is an increasing need to produce new, better qualified personnel. This is best accomplished through providing outcomes-based education that uses defined professional competencies for the specialty group training that comprises the clinical research knowledge base.

Opportunities for clinical research training are available through professional associations such as the Associates of Clinical Research Practitioners (ACRP; www.acrpnet.org), the Society of Clinical Research Associates (SoCRA; www.socra.org), and Drug Information Association (DIA; www.diahome.org). These organizations provide certifications, coordinate meetings, publish journal articles, and offer online continuing education activities, including social networking. Specialized training organizations, such as Barnett International (www.barnettinternational.com) and RXTrials (www.rxtrialsinc.com), offer a variety of courses for clinical researchers that provide additional continuing education.[5,6] Centerwatch (www.centerwatch.com) and independent authors[7-11] have published a variety of "how-to" books on clinical research topics. Online professional or trade association journals, such as *Applied Clinical Trials*, *Clinical Trial Magnifier*, and *Journal of Clinical Research Best Practices*, are available electronically to clinical researchers in any part of the world to gain information and learn "best practices" in the profession.[12-14] What used to be a scarcity of published information on roles, methods, and best practices in the early 1990s is now a widely available collection of literature.

Many individuals seek to achieve their personal and professional goals in the clinical research profession through academic scholarship. This has resulted in the development of more than 50 academic programs in clinical research at accredited educational institutions. Many of these courses are available online or in blended (part live, part online) fashion. The National Institutes of Health (NIH)-sponsored Clinical and Translational Science Award (CTSA) institutions[15] provide post-doctoral coursework for physicians and doctoral-prepared scientists, with the goal of producing interdisciplinary clinical researchers who can help close the traditionally wide gap between benchwork discovery and clinical application. Some of those programs also offer certificates and courses to experienced professionals with master's degrees, whereas in the past, such courses only were available to MDs and PhDs. Other programs, at both the certificate and

master's degree level, have developed both within the United States and around the world to educate the clinical research workforce. Three U.S. nursing schools now offer master's of science in nursing (MSN) programs in clinical research for BSN-prepared RNs,[16-18] and many others are associated with varying certificate programs.

The clinical research profession now includes many responsibilities beyond the traditional roles of collecting and analyzing data from clinical trials. Alternative means of finding new treatments, based either on historical controls or on researching electronic medical records, as well as the availability of new patient treatments have created the field of comparative effectiveness research (CER).[19] FDA also recently called for the creation of new professional roles, such as regulatory scientists and information sciences, to better address the complex needs of pharmaceutical development.[20-22] Interdisciplinary teams in private/public partnerships are becoming more important each year as the complexity of drug development continues to increase in this era of health care reform and spiraling costs.[22]

Outcomes-based Education for Clinical Research Education: Why, How, and Where?

Outcomes-based education (OBE) is results-oriented education and offers best practice guidelines in clinical and clinical research education. It describes not just what learners should "know," but also what learners should be able to "do" at the culmination of their learning experience. OBE is learner-centric and begins with a "clear picture of what is important for students to be able to do."[23] Jessup highlights OBE as the doorway to learning and assessment.[24] Killen describes four principles of OBE:

- Clarity of focus — describing in detail what you want the learners to do
- Designing back — providing clear definitions of the learning that is to be achieved
- High expectations — requiring deep engagement, critical thinking, and the ability to do difficult things well
- Expanded opportunities for learners — providing a variety of different learning strategies.25

Constructivist Learning

Constructivist learning theory, which has its roots in earlier work from John Dewey and Maria Montessori, is inquiry-based, is social, and can be applied in OBE, especially to online teaching platforms to fit a variety of learners in the social context of learning.[26] Harden and colleagues illustrated a three-layered circle as an outcome model of constructivist learning that describes constructivist learning theory.[27] The inner circle represents the tasks completed — "doing the right thing in the role." The middle circle represents the approach taken to achieve the tasks "doing the thing right" and the outer circle represented the personal and professional attitudes of the individual — "the right person doing it." Lock and Redmond also illustrate a social constructivist learning theory that uses three "intersecting" circles that combine (1) "developing and maintaining teaching presence," (2) "exploring cognitive presence," and (3) "fostering social presence" to "create knowledge in action" as an ultimate outcome.[26] This model uses scaffolding learning, the sustaining of a learning community, and participating in social discourse. Finally, Davis notes several major advantages to OBE including:

1. Relevance — content and outcomes are relevant to practice
2. Controversy — research and discourse will improve learning to sort through best practices
3. Acceptability — practice outcomes based on evidence-based learning (EBL)
4. Clarity — gaining understanding based on EBL
5. Framework — curriculum designed based on EBL outcomes
6. Accountability — curriculum meets needs of stakeholders, accrediting bodies and students
7. Self-Directed Learning — focused on student-centered approaches to learning
8. Assessment — learning objectives and evaluation are linked to expected outcomes
9. Curriculum Planning — course development and curriculum are linked to expected outcomes
10. Curriculum Evaluation — accreditation of curriculum by professional bodies are linked to expected outcomes
11. Continuum of Education — learning is ongoing, and requires an evolution of content and experience and continuing education for evolving practice.28

OBE offers a good framework in which to plan, execute, and evaluate educational programs for the widely varying

skills needed by the workforce that conducts the clinical research enterprise. The laudable endpoint of developing such programs is to facilitate the safe and efficacious production of medicinal products for the general public. To reach that endpoint, however, requires that we establish educational and workforce goals within each specialty, describe clear pathways for CRPs to achieve those goals, and monitor student progress toward achieving them.

Issues in Developing Competencies

A "core competency" is a specialized area of expertise that results from merging complex work activities and technology streams together.[29] Gallon et al suggest using the following schema for developing core competencies:

1. Formulate a dedicated task force
2. Inventory all stakeholder capabilities
3. Assess strength and importance of the individual capabilities
4. Examine clusters of complementary critical capabilities
5. Reorganize and streamline domains of competencies (narrowing the field)
6. Define specific capabilities of each domain in behavioral terms (knowledge, skills and attitudes)
7. Test the competencies
8. Evaluate[30]

Developing Competencies for Professionals Involved in Clinical Research and Medicines Development

Several groups currently are working to define competencies and domains of practice for specific groups of clinical researchers. There are many opportunities for CRPs to become involved in and contribute to the definition of competencies within their own specialty. Core competencies and domains of practice for physician and nursing groups are described below. Additionally, the Consortium of Academic Programs in Clinical Research (CoAPCR.org) has been working to define and establish core competencies for the academic programs that educate individuals in clinical research. Together, these activities illustrate the similarities of practice in clinical research that mark the pathway for multidisciplinary research activities.

PHYSICIAN/INVESTIGATOR GROUPS

Academy of Physicians in Clinical Research

In 2010, the Academy of Pharmaceutical Physicians and Investigators (APPI) (now the Academy of Physicians in Clinical Research [APCR]) developed a working group to study and develop proficiency areas for qualifying physician investigators. In 2011, this group published a consensus statement on the topic.[31] The statement divided physicians into three levels, based on their clinical research experience.

Level I — These physicians have been exposed to clinical research and have minimal training in its conduct and procedures. They are considered competent to explain studies to prospective patients or others outside of the direct field of clinical research, but they lack necessary training or experience to serve as principal investigators.

Level 2 — These physicians have had some level of CME training in clinical research, are dedicated to ongoing learning in clinical research concepts and activities, and have participated in 5-20 clinical research studies. Level 2 physicians are qualified to conduct Phase 3 studies, investigator-initiated studies, observational and post-marketing studies.

Level 3 — These physicians are investigators who are committed to clinical research as a major element of their profession. They have conducted more than 20 clinical studies and have successfully completed a qualifying examination to demonstrate their proficiency in CR competencies as established by APPI. They are qualified to conduct Phase 1 and 2 studies as well as Phase 3 studies, investigators-initiated studies, and post-marketing studies.

APCR has identified several specific areas of CR proficiency. These are:

1. Ethics and subject protections
2. Scientific concepts
3. Subject care
4. Operational excellence and regulatory compliance
5. Leadership and business management31

International Federation of Associations of Pharmaceutical Physicians

The International Federation of Associations of Pharmaceutical Physicians (IFAPP) is a non-profit organization of physicians who focus on the development of training and continuing education programs in pharmaceutical medicine. This group, which has been functional since 1978, has specifically addressed questions regarding the global expansion of clinical research.[32] The IFAPP has identified eight competency domains for continuing education and training:

1. Discovery of medicines and early development planning
2. Clinical development
3. Clinical trials
4. Medicines regulation
5. Drug safety surveillance
6. Health care marketplace
7. Interpersonal communication and management skills
8. Ethics and subject

NURSING GROUPS

NIH CRN2010

A Clinical Research Nurse 2010 Working Group, chaired by Clare Hastings, Chief Nursing Officer of the NIH Clinical Center, executed an initiative to define nursing competencies in clinical research in the NIH CRN2010 project.[33,34] The committee was comprised of experienced clinical research nurses who served as content experts in reviewing domains and competencies over several anonymous editorial rounds known as a "Delphi approach"[35] to gain consensus among expert CRNs. Five CRN domains of practice were identified that characterize the role of nurses in clinical research.[36] The five domains for clinical research nursing are:

1. Clinical practice
2. Human subject protection
3. Contributing to the science
4. Care coordination and continuity
5. Study management

A total of 59 distinct roles falling under the five categories have been identified and tested through a Delphi approach using experts to categorize and agree to several anonymous rounds of editing and agreement of terms validated through broader surveys to CRNs. Research is continuing on better defining nursing contributions in clinical research at varying levels of patient care using these criteria, and several new sets of clinical research nurse coordinator roles and responsibilities have been identified as a result of this effort. These roles and responsibilities are described in a recently published study comparing work-related differences in responsibility between two nursing groups working at the NIH Clinical Center: Clinical Research Nurses (CRNs) and Research Nurse Coordinators (RNCs).[37]

International Association of Clinical Research Nurses

The International Association of Clinical Research Nurses (www.iacrn.org) was formed in 2008 as a Professional Nursing Organization. Its purpose is to define, validate, and advance clinical research nursing as a specialty practice along with supporting the professional development of registered nurses who directly or indirectly impact the care of clinical research participants. IACRN was founded by a subset of Nurse Managers from the General Clinical Research Center Nurse Manager Organization who recognized the need to create an organization to represent the specialty practice of clinical research nursing. Since its inception the organization has been working to define the scope and standards for clinical research nurses. IACRN has adopted the American Nurses Associations format for standards and competencies with the goals of pursuing ANA recognition as a nursing specialty.[38] The organization is using a "Modified Delphi" approach to define the standards among clinical research nurse experts in a diverse range of settings and roles by gaining consensus through a series of rounds of "content edits." The organization expects that this process will be completed and published within the next year. IACRN believes the establishment of professional standards and best practices for all CRNs will ensure quality research practices, high ethical standards, regulatory compliance, and human subjects' protection.

Oncology Nursing Society

The Oncology Nursing Society (ONS) has identified key competencies for clinical research nurses working with oncology clinical trials. The Society provides certification to its members who pass a training course examination, and promotes research on best practices in the training of novice oncology clinical research nurses.[39] Clinical trials are a necessary factor in improving outcomes for people with or at risk for cancer. Cancer patients have complex needs, and oncology clinical trials put heavy demands on nurses. The Oncology Nursing Society (ONS) believes that nurses with knowledge about cancer care and clinical research are essen-

tial to the effective conduct of cancer treatment and prevention trials.[40] A growing number of ONS members identify clinical research as their primary job focus. However, there is great variability in how the role of the nurse on the research team is defined and implemented. For these reasons, ONS leadership initiated the development of a core set of clinical trials nursing competencies to standardize role expectations and highlight the specific contributions of the nurse. The focus of these competencies is on the nurse with two or fewer years' experience as a CTN because these individuals have limited knowledge and access to fewer resources than more experienced nurses.[41] ONS uses the term CTN for the specialty nursing role focused on the coordination of clinical trials and the care of people on clinical trials. This term was adopted to ensure consistency across special interest groups and publications.

The Oncology Clinical Trials Nurse (CTN) Core Competencies were developed using a three-step process. The process began by drafting of an initial set of competencies based on a review of literature, opinions of experts in the field and results of a survey of current oncology CTN's. A field review was then performed to evaluate how well the draft competencies reflected current CTN practice. Finally, the competencies were validated by expert review. At each step in the process, the competencies were refined and clarified.[41,42]

The result of this process was the delineation of 9 functional areas and 54 competency statements within these functional areas. The functional areas include

- Protocol compliance
- Clinical-trials related communication
- Informed consent process
- Management of clinical trial patients
- Documentation
- Patient recruitment
- Ethical issues
- Financial implications
- Professional development[41]

These competencies are helpful to novice CTNs in defining and becoming competent in their new role. In addition, the competencies will help other clinical organizations develop distinct position descriptions within their own specialty, and develop CTN orientation materials and performance appraisal.[41]

UK Competency Framework Working Group

The United Kingdom National Health Service has acknowledged the evolving specialty of clinical research nurses. In 2008, it published a draft competency framework for clinical research nurses and has continued to evolve this document to encompass this expanding nursing role in the U.K.[43]

CRNs make a significant contribution to high quality clinical research in the United Kingdom. For many years in the United Kingdom, the workloads and responsibilities of CRNs varied considerably between different research sites and specialties. As a result of significant investment from the UK government, there now exists a clinical research infrastructure and a series of research networks that employ many different research personnel. A number of competency documents have been produced, by different groups and networks that support clinical research. In 2007 these groups collaborated to produce A National Competency Framework for Clinical Research Nurses,[44] which could be used by all CRNs in any setting.

The Competency Framework offers a process through which CRNs can demonstrate the acquisition and application of the knowledge and skills required by CRNs. It consists of four main areas, each of which is considered to be common to all CRN roles. Those competencies are:

1. Demonstrating an understanding of the background, political influence and strategy regarding clinical research in the UK

2. Working within, and adhere to, the requirements of research ethics, research governance and legislation

3. Understanding apply and promote the principles and practice of obtaining informed consent

4. Applying professional knowledge and skills to facilitate efficient, safe and participants focused clinical research

More recently, a management skills competency level has been added. The second volume of the Framework[45] is now being used in numerous settings in the UK, and forms the basis for personal development programs for many CRNs.

Educational Competencies in Clinical Research

Clinical and Translational Science Award

The NIH National Center for Research Resources (NCRR) established the CTSA program to fund a consortium of

more than 60 medical research institutions in 30 states and the District of Columbia. In December 2011, the NIH established the National Center for Advancing Translational Sciences (NCATS) to address bottlenecks in the translational pipeline and to speed the delivery of new drugs, diagnostics and medical devices to patients (www.ncats.nih.gov). The CTSA awards are now coordinated under NCATS.[46] The goal of the CTSA program is to transform clinical research by speeding translation of bench research to new treatments for patients and to engage communities in clinical research efforts. The program is training new clinical and translational researchers from many medical disciplines. The CTSA has identified core competencies for master's degree level education to include the following domains:

- Clinical and translational research questions
- Literature critique
- Study design
- Research implementation
- Sources of error
- Statistical approaches
- Biomedical informatics
- Clinical research interactions
- Responsible conduct of research
- Scientific communication
- Cultural diversity
- Translational teamwork
- Leadership
- Cross-disciplinary training
- Community engagement[47]

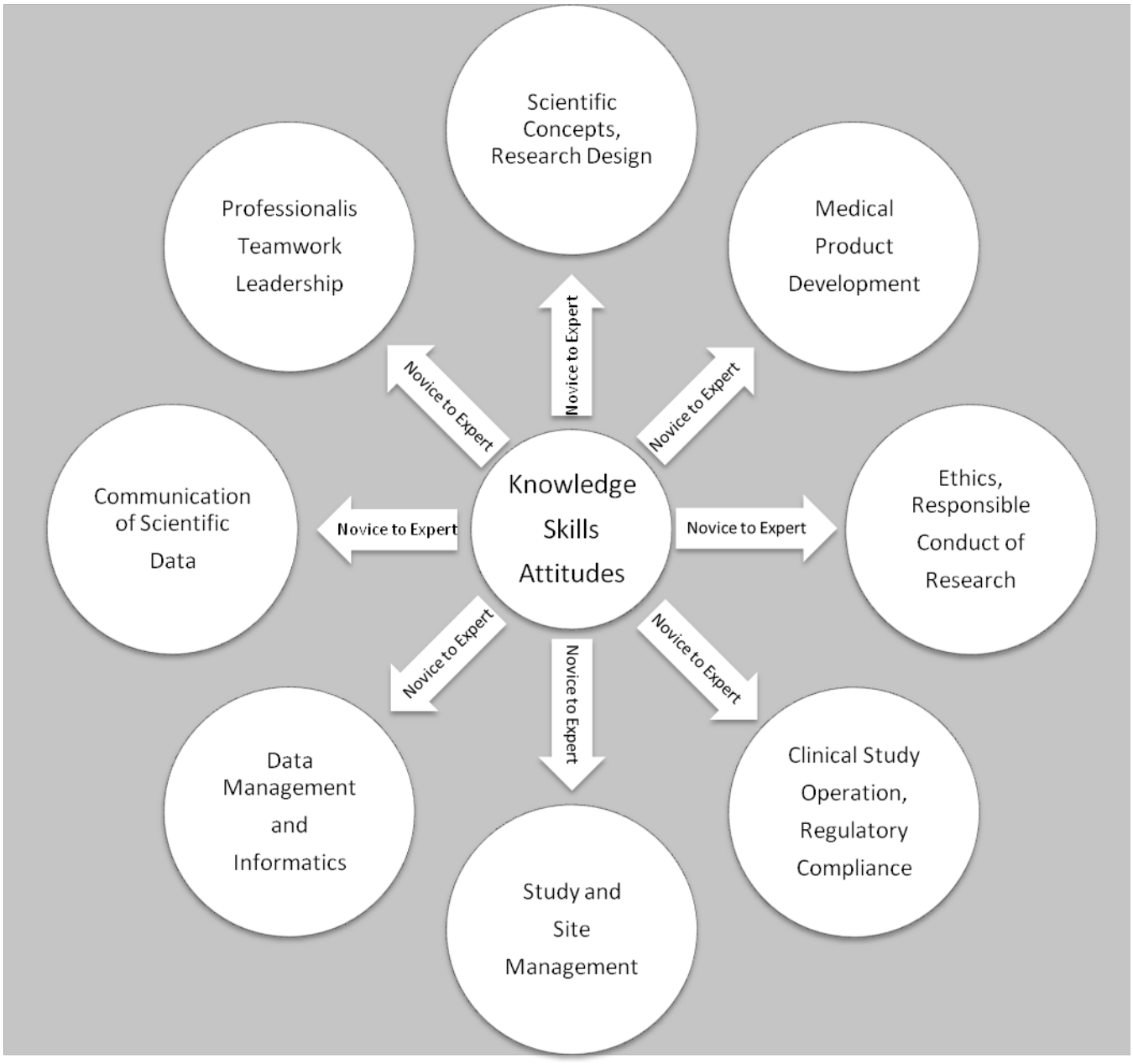
Consortium of Academic Programs in Clinical Research

In 2003, the Consortium of Academic Programs in Clinical Research (CoAPCR) was formed to provide a forum for sharing among academic programs in clinical research, to identify core competencies that should be included in curriculum of such programs, and ultimately to provide a pathway for accreditation of those programs. The process of identifying core competencies among educational programs required a survey of ongoing academic programs and the work of other organizations, described above, in defining and validating domains of practice and competencies. Understanding pharmaceutical, medical, nursing, regulatory, statistical, and industry stakeholders and their domains of practice and operation were paramount. Where will the graduates of existing programs be hired? What roles do individuals in clinical research based on education, training, and experience fill? What regional needs are there for well-trained graduates? Where are the gaps and hiring practices? CoAPCR members sought to identify differences between existing educational offerings and whether a graduate degree or a certificate earned from one institution was comparable to one earned from a counterpart institution. Academic programs providing education in clinical research exist in the United States at the associate degree level, the baccalaureate level, post-baccalaureate certificate level, and master's degree level. Their graduates are employed in the pharmaceutical industry, contract research organizations, and private and academic clinical research sites. Establishing competencies that are broad enough to cover all potential academic programs was a challenge to the consortium members. The following eight learning domains have been identified:

1. Scientific Concepts and Principles of Research Design
2. Medical Product Development
3. Ethical Considerations and the Responsible Conduct of Clinical Research
4. Clinical Study Operation and Regulatory Compliance
5. Study and Site Management
6. Data Management and Informatics
7. Communication of Scientific Data
8. Professionalism, Teamwork, and Leadership

For each of these domains, the working committee identified learning objectives in cognitive, psychomotor, and affective learning domains. These learning objectives are based on Bloom's taxonomy of learning and acknowledge Benner's learning theory of novice-to-expert and are intended to be applied based on student educational levels, backgrounds and experiences (*see Figure 1*).[48,49] Future CoAPCR plans include the validation of these eight domains and the development of a process for the accreditation of member academic programs in clinical research through the Commission on Accreditation of Allied Health Education Programs.[50]

Table 1. CoAPCR Competencies



Note: CoAPCR Competencies illustrate the incorporation of learning theories of Bloom and Benner[48,49]

Conclusion

Specialty groups are working to define the roles of individuals who work in specific content areas, including, but not limited to: physician investigators, nurses, employees of sites that conduct clinical trials, as well as pharmaceutical companies and contract research organizations. Evolving specialties in regulatory affairs, project management, implementation science, and comparative effectiveness research may require new levels of competencies to be defined. Following the development of certification examinations by ACRP, APPI, and SoCRA additional clinical research groups such as ONS and IACRN are considering the establishment of certification to address the need for their own specialized areas of competency. A comparison of competencies with the CoAPCR competencies illustrates the overlap of topics being considered by each group (*see Table 1*). Each group is generally aiming at the same target — better education of the future workforce

Table 1. Comparing Core Competencies

CoAPCR	APCR	IFAPP	CTSA	NIH CRN	ONS	UK-CFWG
Ethical consideration and responsible conduct of research	Ethics and subject protections	Ethics and Subject	Responsible conduct of research	Human subjects protection	Ethical issues Informed consent process	Understand, apply, promote principles and practice of informed consent Working within and adhere to the requirements of research ethics, research governance and legislation
Scientific concepts and principles of research design	Sc ientific concepts	DIscovery of medicines and early development planning	Clinical and translational research questions Literature critique Study design Sources of error Statistical approaches	Contributing to science		Understand background, political influence, and strategy regarding clinical research in the United Kingdom
Clinical study operation and regulatory compliance*	Subject care	Clinical development	Community engagement	Clinical practice Care coordination and continuity	Protocol compliance Management of clinical trial patients	Apply professional knowledge and skills to facilitate efficient, safe, and participant-focused clinical research*
Medical product development Clinical study operation and regulatory compliance	Operational excellence and regulatory compliance	Clinical trials Medicines regulation	Research implementation	Care coordination* and continuity Study management	Documentation Patient recruitment Informed consent process*	Apply professional knowledge and skills to facilitate efficient, safe, and participant-focused clinical research
Study and site management Data management and informatics Communication of scientific data Professionalism, teamwork and leadership	Leadership and business management	Health care marketplace Interpersonal communication and management skills	Biomedical informatics Clinical research interactions Scientific communication Cultural diversity Translational teamwork Leadership Cross-disciplinary training	Study management* Contributing to the science*	Financial implications Clinical trial related communication	Management skills

Note: * = indicates that this competency additionally fits into a second category area

of scientists and clinicians in clinical research. The recent work on developing core competencies in clinical research, which is described here, suggests that a turning point has been reached in the clinical research enterprise It indicates that the clinical research professionals themselves wish to claim specialty credentials in the enterprise. Establishing and

recognizing new levels of competency will result in higher quality clinical research outcomes where roles are better defined and where benchmarks for best practices in clinical research can be established. These benchmarks will, in turn, improve the quality and safety of and will be particularly valuable as studies continue to increase in complexity but are further constrained by economic factors. Differentiating and embracing roles and responsibilities within and across the clinical research specialties can ensure that patients and the public have access to competent interdisciplinary teams, innovative approaches to patient care and the conduct of ethical and safe clinical trials.

References

1. Mueller M. From delegation to specialization: Nurses and clinical trial coordination. *Nursing Inquiry* 2001;8:182-190.
2. Gwede CK, et al. Burnout in clinical research coordinators in the United States. *Oncol Nurs Forum* 2005;32:1123-1130.
3. Bell J. Towards clarification of the role of research nurses in New Zealand: A literature review. *Nurs Praxis N Z* 2009:25: 4-16.
4. Poston RD, Buescher CR. The essential role of the clinical research nurse (CRN). *Urol Nurs* 2010;30:55-77.
5. Barnett International. Barnett Educational Services. 2012.
6. Rx Trials Institute. The RxTrials Institute. 2012.
7. Gallin JI, Ognibene FP. *Principles and Practice of Clinical Research.* New York: Elsevier; 2007.
8. Emanuel EJ, et al. *Ethical and Regulatory Aspects of Clinical Research.* Baltimore: Johns Hopkins University Press; 2003.
9. Friedman LM, et al. *Fundamentals of Clinical Trials.* New York: Springer; 2010.
10. Shamoo AE, Resnik DB. *Responsible Conduct of Research.* New York: Oxford University Press, Inc.; 2009.
11. Stone J. *Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators and Investigators.* Cumberland, Maryland: Mountainside MD Press; 2010.
12. CT Magnifier. *Clinical Trial Magnifier.*
13. ACT. Applied Clinical Trials. In: *Applied Clinical Trials.*
14. First Clinical. *Journal of Clinical Research Best Practices.*
15. CTSA Consortium. CTSA Institutions. 2012.
16. UAB School of Nursing. Clinical Research Management Specialty. Birmingham, AL; 2010.
17. Drexel School of Nursing. MSN in Clinical Trials Research. 2011.
18. George Washington University School of Nursing. Clinical Research Management MSN Program. Washington, DC; 2012.
19. Concato J, et al. Comparative effectiveness research: What kind of studies do we need? *J Invest Med* 2010;58:764-769.
20. Olson S, Claiborne AB; Forum on Drug Discovery, Development, and Translation, IOM. *Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary.* The National Academies Press; 2012.
21. U.S. Food and Drug Administration. Advancing regulatory science for public health. In: Administrator USFaD, ed. A framework for FDA's regulatory science initiative. Washington, DC: U.S. Food and Drug Administration; 2010.
22. Damschroder LJ, et al. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Imlement Sci* 2009;4:50.
23. Spady WG. Organizing for results: The basis of authentic restructuring and reform. *Educational Leadership.* 1988;October:4-8.
24. Jessup G. *Outcomes: NVQs and the emerging model of education and training.* London: Farmer Press; 1991.
25. Killen R. *Outcomes-based education: Principles and possibilities.* Unpublished. Newcastle, Australia: University of Newcastle, Faculty of Education; 2000.
26. Lock JV, Redmond P. International online collaboration: Modeling online learning and teaching. *J Online Learn Teach* 2006;2:233-247.
27. Harden RM, et al. An introduction to outcome-based education. *Med Teach* 1999;21:7-14.
28. Davis MH. Oucome-based education. *J Vet Med Educ* 2003;30:227-232.
29. Prahalad CK, Hamel G. The core competence of the corporation. *Harvard Business Review.* 1990(May-June):79-91.
30. Gallon MR, et al. Putting core competency thinking into practice. *Res Technol Mgmt* 1995;38:20-29.
31. Koren MJ, et al. APPI Physician Investigator Competence Statement. *The Monitor.* 2011;25:79-82.
32. International Federation of Associations of Pharmaceutical Physicians. 2012.
33. Committee CDoP. *Building the Foundation for Clinical Research Nursing: A Clinical Research Nursing Model of Care.* Bethesda, MD: National Institutes of Health Clinical Center, Nursing and Patient Care Services; 2009.
34. CRN 2010 Domain of Practice Committee. Building the foundation for clinical research nursing: Domain of practice for the specialty of clinical research nursing. National Institutes of Health Clinical Center, Nursing and Patient Care Services; 2009.
35. Okoli C, Pawlowski SD. The Delphi method as a research tool: An example, design considerations and applications. *Inform Mgmt* 2004;42:15-29.
36. Castro K, et al. Validating the clinical research nursing domain of practice. *Oncol Nurs Forum* 2011;38:E72-E80.
37. Bevans M, e al. Defining clinical research nurse practice: Results of a role delineation study. *Clin Transl Sci* 2011;4:421-427.
38. American Nurses Association. *Nursing: Scope and Standards of Practice.* Silver Springs, MD: Nursesbooks.org; 2010.
39. Oncology Nursing Society. Oncology clinical trials nurse competencies. In: *Oncology Nursing Society*, ed. Pittsburgh, PA; 2010.
40. Oncology Nursing Society. Oncology nursing society position: Cancer research and clinical trials; 2009.
41. Lubejko B, et al. Oncology clinical trials nursing: Developing competencies for the novice. *Clin J Oncol Nurs* 2011;15:637-643.
42. Daugherty P, et al. Oncology clinical trials nurse competencies. In: Society ON, ed. Pittsburgh, PA: Oncology Nursing Society; 2010.
43. UK Clinical Research Collaboration Subcommittee for Nurses in Clinical Research. Developing the best research professionals: Qualified graduate nursees: Recommendations for preparing and supporting clinical academic nurses of the future. In: UK Clinical Research Collaboration, ed. Report. London, United Kingdom; 2011.
44. Competency Framework Working Group. A National Competency Framework for Clinical Research Nurses. Competency Framework Working Group; 2008.
45. Competency Framework Working Group. Competency framework for clinical research nurses: A tool to promote patient safety and quality data. 2nd ed: Competency Framework Working Group; 2011.
46. Collins FS. Reengineering translational science: The time is right. *Sci Translati Medi* 2011;3(90cm17).
47. Consortium C. *Core Competencies.* 2012.
48. Benner P. *Excellence and Power in Clinical Nursing Practice.* Menlo Park: Addison-Wesley; 1984.
49. Bloom BS. *Taxonomy of Educational Objectives.* Boston: Pearson Education; 1984.
50. CAAHEP. Commission on Accreditation of Allied Health Education Programs.