

Candidate Handbook

Clinical Research Nurse Certification by Portfolio

Introduction

Certification has been defined by the American Board of Nursing Specialties (ABNS, 2005) as “the formal recognition of the specialized body of knowledge, skills, and experience demonstrated by the achievement of standards identified by a nursing specialty to promote optimal health outcomes” (para. 1).

Specialty nursing certification is relevant to every area of nursing practice. Nurses across nursing roles and practice settings can impact health care quality by demonstrating their specialty knowledge and their commitment to lifelong learning through certification.

Continuing competence is the ongoing professional responsibility of a clinical research nurse to obtain, integrate, and apply current knowledge and skills required to practice safely, effectively, and ethically in designated roles and settings.

A workgroup of subject matter peers was established by the International Association of Clinical Research Nurses (IACRN) to explore clinical research nursing certification by portfolio. As the basis for certification development, the work group defined continuing competence as:

- A professional and ethical obligation for safe practice.
- Protection of the public and advancement of the profession through ongoing development of individual nurses.
- A shared responsibility among individual nurses, the profession, regulatory bodies, certification agencies, professional associations, educators, and care organizations/workplaces.
- Evolving as it builds upon previous competence and integrates new evidence.
- Dynamic, fluid, and impacted by many factors as nurses enter new roles and new settings.

An important goal of specialty certification is consumer protection—to ensure consumers receive health care from knowledgeable clinical research nurses. Recertification procedures were developed as part of CRNCC’s efforts to ensure the continuing competence of its certificants.

Clinical research nursing is the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol. This specialty practice incorporates human subject protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management throughout a variety of professional roles, practice settings, and clinical specialties.

Certification as a clinical research nurse demonstrates the individual’s commitment to practice excellence, continuing competence, and lifelong learning. The CRN-BC™ credential represents the only nursing certification that recognizes expertise as a clinical

research nurse. It is earned through completion of a professional portfolio that validates the applicant's role performance in clinical research nursing.

Elements of the portfolio are described in this handbook. Briefly, candidates must

- Complete a minimum number of contact hours of continuing education in clinical research.
- Choose at least two of five professional development options to document their *expertise and engagement* in the role of clinical research nurse.
- Write an exemplar describing their performance in four key areas: professional growth, professional and ethical practice, team focus and interprofessional collaboration, and quality and safety.
- Provide a copy of the current curriculum vita/resume.

Samples of professional development points accrual are included on pages 10-11 of this handbook to demonstrate how required points can be earned in the 5 years preceding application for certification by portfolio.

American Board of Nursing Specialties. (2005). A Position Statement on the Value of Specialty Nursing Certification. Retrieved from http://www.nursingcertification.org/resources/Documents/research/value_certification.pdf

CERTIFICATION:

This process is to be used when applying for initial certification by portfolio, when reapplying for a certification that was denied, or when reapplying for certification after expiration of the original certification. For renewal of an existing (current) certification, refer to the recertification section.

Audits of incoming applications will occur on a regular basis, at about the rate of 1 out of every 10 applications. The review committee reserves the right to audit an application at their discretion. It is advised that as the applicant is completing the application process he/she create a file of the documents that will be required should an audit occur.

Step 1 – Confirm Practice Hours and Licensure.

To be eligible for CRN-BC certification by portfolio, the registered nurse must meet the following requirements:

Licensure

- Current and unencumbered RN license
- 2 years minimum as an RN at time of application for certification

Specialty Practice

- Minimum 4000 practice hours in the clinical research nurse role (not including hours in residency or orientation) in the previous 3 years at time of application for certification:

Step 2 – Complete Continuing Education Record.

- Provide continuing education record (see *Forms*) to list all CE activities.
- Handwritten records or CE/CPD transcripts will not be accepted.
- Should you be audited, CE/CPD certificates will be requested.

Category 1. Continuing Education - Minimum 36 points, maximum 50 points.

Continuing education 36 hours minimum in ***clinical research*** in the previous 3 years (e.g., average one webinar per month). One point per CE or CPD. No general nursing topics will be accepted for initial certification.

Continuing education must be offered by an approved provider of:

- Nursing education (CNE)
- Continuing medical education (CME)
- Continuing professional development (CPD) hours

For example, relevant education can be completed through the following organizations, if the educational offering is approved by an accredited provider of CNE/CME/CPD:

- Society of Clinical Research Associates (SoCRA)
- Society for Clinical Trials (SCT)

- Public Responsibility in Medicine and Research (PRIM&R)
- Accreditation Council for Pharmacy Education (ACPE)
- Association of Clinical Research Professionals (ACRP)
- National Research Organization conferences (e.g., UKCRF Network, NIHR)

All topics must be specific to clinical research. Courses may be used only once in the application. Credit is not given for Basic Life Support (BLS), Advance Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS) or BLS, ACLS, PALS instructor courses or Collaborative Institutional Training Initiative (CITI program). *The applicant must provide evidence of meeting category #1 above, by providing the Continuing Education Report (see forms).*

In addition to meeting the minimum continuing education requirement, the applicant must provide evidence of activity in a minimum of two of the five professional development activities categories, in Step 3 below, to earn the remaining 50-64 points. The combination of CE points (Step 2) and professional development activities points (Step 3) must equal the required total of 100 points.

Please note:

The applicant may submit activities in all of the categories in Step 3, if needed, to reach the required points for professional development activities.

Professional development points may be earned at any time during the 5-year window preceding submission of an application for certification (e.g. earn points in any one or more years or accrue points throughout the 5 years). See point accrual examples on pages 10-11

Step 3 – Document Professional Development Activities.

Professional Development Activities with Operational Definitions

All activities must be completed in the 5 years preceding application for certification by portfolio.

Please Note:

In the following categories (2-6), only clinical research activities can be applied to application for initial certification by portfolio; no general nursing topics will be accepted.

Category 2.

Clinical research podium and poster presentations, and webinars/podcasts - Maximum of 35 points. Presentations (both virtual and in-person) may be used only once in the application. For example, credit cannot be given for two presentations of a certification review course.

Presentations:

- Podium presentations of templated material (**content not developed by the presenter**), presented as a professional nursing or clinical research activity:

Each 1 hour of podium presentation = 1 point (must be 30-60 minutes in length)

- b. Original community or hospital/unit-specific presentation (in-service) **not offered for CE credit (i.e., not vetted by approved provider):**
Each 30 minutes of presentation = 1 point (1-hour presentation = 2 points)
- c. Original podium presentation at a professional nursing or clinical research conference or educational activity **offered for CE credit (i.e., vetted by approved provider):** Each 30 minutes of podium presentation = 2 points (e.g., 1-hour presentation = 4 points; points awarded the same for all presenters if there are multiple speakers)

Webinar/Podcast:

- a. Webinar/podcast of templated material (**content not developed by the presenter**), as a professional nursing or clinical research activity:
Each 30 minutes of presentation = 1/2 point (1-hour presentation = 1 points)
- b. Original webinar/podcast presented as a professional nursing or clinical research activity **not offered for CE credit (i.e., not vetted by approved provider):**
Each 30 minutes of presentation = 1 point (1-hour presentation = 2 points)
- c. Original webinar/podcast presented as a professional nursing or clinical research educational activity **offered for CE credit (e.g., vetted by approved provider):**
Each 30 minutes of webinar/podcast presentation = 2 points (e.g., 1-hour presentation = 4 points)

Poster:

- a. Original community or hospital/unit-specific poster (in-service) **not offered for CE credit (i.e., not vetted by approved provider):**
Poster development and presentation = 2 points
Poster development (co-developer) = 1 point
- b. Original poster presentation at a professional nursing conference or clinical research conference or educational activity **offered for CE credit (e.g., vetted by approved provider):**
Poster development and presentation = 3 points
Poster development (co-developer) = 2 point

Round table:

- a. Round table leadership = 1 point

All content must be related to clinical research. If the applicant is audited, a copy of the presentation PowerPoint or poster, a copy of the conference agenda, or a letter of acknowledgement from the event organizer that stipulates title and date of presentation must be submitted upon request.

Category 3. Scholarly editing and writing – Maximum of 35 points. Publications may be used only once in the application. Authorship on a publication must meet the International Committee of Medical Journal Editors' criteria (please see website definition): <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

- a. Author of hospital or unit-based/research-specific policies/standards of practice = 2 points per policy/SOP
- b. Authorship of a column in a professional nursing newsletter = 2 points
- c. Authorship of abstract or meeting proceedings **published** in a professional nursing journal = 3 points
- d. Editor of research-specific hospital/department newsletter = 4 points
- e. Editor of chapter newsletter for professional nursing organization (e.g., IACRN, ONS) = 5 points
- f. Authorship of CE module for a commercial vendor = 5 points
- g. Authorship of article **published in a non-refereed/non-peer-reviewed journal** (e.g., ACRP) = 7 points for first author; 5 points for other authors
- h. Authorship of article **published in a refereed/peer-reviewed journal** = 10 points for first author; 8 points for other authors
- i. Authorship of or contributor to professional specialty document (e.g., Scope & Standards) = 8 points
- j. Author of a recurring column in a professional nursing journal = 8 points
- k. Authorship of chapter in published book; single topic on CD or audiotape = 10 points
- l. Guest editor for one issue of professional nursing journal = 10 points
- m. Editor of a professional nursing newsletter = 10 points for a minimum of 1 year in the role
- n. Section editor of a professional nursing book = 15 points
- o. Authorship of entire book, CD, audiotape = 20 points
- p. Editor of entire professional nursing book = 20 points
- q. Editor of a professional nursing journal = 20 points

If the applicant is audited, a copy of the publication must be submitted upon request. If this is not possible (e.g., CD/audiotape or thesis/dissertation), a letter of acknowledgement must be submitted from the publisher.

Category 4. Research and Scholarly Projects – Maximum of 35 points. Credit is given for original research as well as CQI and EBP projects.

- a. CQI/EBP with clinical research focus **unpublished** = 5 points for primary investigator, 3 points for co-investigator
- b. Original research **unpublished** = 6 points for primary investigator, 4 points for co-investigator
- c. Completed original/applied research **published** (except thesis/dissertation), meta-analysis, systematic/integrative review = 10 points for primary investigator, 8 points for co-investigator
- d. Chair or member of thesis/dissertation committee for nursing or allied health discipline = 8 points

- e. Chair or member of IRB = 8 points for chair, 5 points for member **per year**
- f. PhD dissertation from nursing or allied health discipline = 20 points
- g. DNP scholarly project = 15 points
- h. Master's thesis from nursing or allied health discipline = 10 points
- i. BSN CQI/EBP/capstone project = 5 points

If the applicant is audited, a formal abstract must be submitted upon request for any unpublished/not yet published work. A copy of the IRB determination must be forwarded if audited. A copy of the university transcript demonstrating completion of the scholarly project/thesis/dissertation must accompany the portfolio application.

If research or EBP/CQI project is completed and published, points may be claimed in both category #3 and category #4.

Category 5. Professional activities – Maximum of 35 points. Credit is given for leadership roles and active participation in nursing organizations or initiatives that exceed expectations/duties of the employment position held at the time the activity was conducted.

- a. Facilitate clinical research activity in the practice setting (e.g., chair weekly protocol team meetings, lead monthly meetings of a specific research group, train study teams) = 2 points **per year**
- b. State, regional, or national award related to clinical research = 2 points
- c. Officer of national specialty nursing organization = 3 points **per year**
- d. Officer of local chapter of specialty nursing organization = 3 points **per year**
- e. Committee member or chair for hospital-based or unit-based research council = 3 points **per year** (has attended 50% or more of meetings in service term)
- f. Committee member for local community initiative related to clinical research = 3 points **per year** (has attended 50% or more of meetings in service term)
- g. IACRN Committee chair or member = chair 5 points per year; members 3 points **per year** (has attended 50% or more of meetings in service term)
- h. Mentorship of novice investigators in protocol development and implementation – 80 hours of mentorship = 5 points (verification form required-see forms); maximum of two 5-point awards in the application
- i. Preceptorship of RN students or clinical research professionals: 80 hours of preceptorship = 5 points (verification form required-see forms); maximum of two 5-point awards in the application
- j. Nurse representative to a national or regional initiative related to clinical research (e.g., advisory board for a CTSA) = 5 points **per year** (has attended 50% or more of meetings in service term)
- k. Chair or member of community advisory board related to community research = 5 points **per year** (has attended 50% or more of meetings in service term)
- l. IACRN Board of Directors = 5 points **per year**

If the applicant is audited, a letter must be submitted from the nursing organization or the event organizer to verify the applicant's role for any of the above activities upon

request. In addition, a preceptor and/or mentorship verification (see forms) must be submitted for any claimed hours.

Category 6. Advanced academic education (personal study) in the following courses only: Methods, Statistics, Research, Translational Science – Maximum of 35 points. Credit will not be given for general education or other nursing courses.

- a. Semester work - 1 academic credit = 15 points
- b. Quarter work - 1 academic credit = 12.5 points
- c. 5 ½ week term - 1 academic credit = 6.25 points

To be used in the portfolio, education must be beyond the applicant's minimum earned degree (e.g., applicant with ADN returns to school for BSN; MSN returns to school for PhD). Please provide a separate statement of the course's specific application to clinical research nursing and your current nursing role. If the applicant is audited, a course description and transcripts may be requested.

Please Note:

Academic teaching is used to meet experiential requirement; it is not a separate professional development activity.

Step 4 – Submit Resume and Exemplar.

Please use the resume template page 12 as a formatting guide to provide information about employment, education, professional affiliations, licenses and certifications, and awards. Information about presentations and publications should be included in Step 3 and not repeated in the resume.

Please complete the exemplar based on the instructions on pages 13-18. A rubric is provided (p.15-18) to demonstrate how the exemplar will be scored. The exemplar is worth 64 points; a passing score of 45 points is required.

The following represent examples of how an applicant might accrue the required points over a 5-year period. However, there is no requirement that points be earned annually; points may be earned at any time during the 5-year period preceding application submission.

**Sample 1– Professional Development Points Accrual
CRN - BC Certification by Portfolio**

50-64 points required based on amount of continuing education submitted

Year 1 (12 points)

Category 2

1-hour unit presentation (not for CE credit) = 2 points

Category 3

Editor, ONS chapter newsletter = 5 points

Category 4

Hospital IRB member = 5 points

Year 2 (43 points)

Category 3

Author, five hospital policies = 5 points

Guest column in IACRN newsletter = 1 point

Category 5

Chair, weekly protocol team meeting = 2 points

Category 6

Completed 3-semester credit “Methods” course as part of MSN program = 45 points (35 maximum accepted in this category)

Year 3 (4 points)

Category 2

Poster presentation, IACRN = 2 points

Category 5

Chair, weekly protocol team meeting = 2 points

Year 4 (6 points)

Category 2

1-hour podium presentation, IACRN = 4 points

Category 5

Chair, weekly protocol team meeting = 2 points

Year 5 (10 points)

Category 4

Master’s thesis = 8 points

Category 5

Chair, weekly protocol team meeting = 2 points

75 total points submitted

**Sample 2 – Professional Development Points Accrual
CRN - BC Certification by Portfolio**

50-64 points required based on amount of continuing education submitted

Year 1 (8 points)

Category 2

1-hour unit presentation (not for CE credit) = 2 points

Poster development = 1 point

Round table leadership = 1 point

Category 3

Editor, research department newsletter = 1 point

Hospital unit research SOP (one point for each) = 3 points

Year 2 (9 points)

Category 2

Podium presentation = 2 points

Category 3

Author, five hospital policies = 5 points

Category 5

Chair, weekly protocol team meeting = 2 points

Year 3 (10 points)

Category 2

Poster presentation, IACRN = 2 points

Category 5

Chair, weekly protocol team meeting = 2 points

Committee member of hospital-based research council = 3 points

IACRN committee member = 3 points

Year 4 (14 points)

Category 2

1-hour podium presentation, IACRN = 4 points

Category 5

Chair, weekly protocol team meeting = 2 points

Mentorship of novice investigators = 5 points

IACRN committee member = 3 points

Year 5 (14 points)

Category 2

Poster presentation, IACRN = 2 points

Category 5

Chair, weekly protocol team meeting = 2 points

Preceptor of RN student in research role = 5

IACRN committee Chair = 5 points

55 total points submitted

NAME, CREDENTIALS

Home Address/Cell or Residential Telephone Number/Email Address

PROFESSIONAL GOALS

Provide a 2-3 sentence summary of your goals as a professional nurse.

EXPERIENCE

Beginning with the most recent position, please list employer, city/state, dates of employment, position, brief description of role responsibilities and hours worked per year.

EDUCATION

Beginning with the most recent degree, please list college/university, city/state, graduation date, earned degree.

PROFESSIONAL AFFILIATIONS

Please list all professional memberships (e.g., specialty nursing organizations, nursing honor society) with dates of involvement. Also identify any leadership positions and dates of service.

LICENSE AND CERTIFICATIONS

Beginning with the most recent document, please list all licenses and specialty nursing certifications. Please do not include certificates such as BLS, ACLS, PALS, or NALS.

AWARDS

Beginning with the most recent award, please identify local, state, and national awards received as a professional nurse.

Exemplar Instructions and Rubrics CRN-BC Certification by Portfolio

Your exemplar should provide evidence of clinical research nursing practice excellence specifically related to the areas described below (16 points for each area; 64 total possible points). Please discuss at least four different activities (one per domain) and *describe how, as a clinical research nurse, they have contributed to your development.* **Note: Minimum of 1,000 and Maximum 1,500 words;** the exemplar should be typewritten and double-spaced, with applicant's name in the upper left corner so it can be redacted for blind review.

Please note:

*Activities discussed in detail in the exemplar may also be documented in Step 3 (Professional Development Activities) to earn the required number of points for the portfolio. **Points earned for the exemplar are separate from the points earned for continuing education and professional development activities.***

Professional Growth – recent or current activities that develop the applicant as a clinical research nurse. Accepted activities include but are not limited to the following:

- advanced education
- professional conference attendance
- poster or podium presentations
- professional award with demonstration of criteria
- nursing research/manuscript development

Professional and Ethical Practice – recent or current activities that contribute to the applicant's ethical practice as a clinical research nurse. Accepted activities include but are not limited to the following:

- active participation/leadership in Shared Governance/other council structure
- active participation/leadership in Magnet Steering Council
- active participation/leadership in facility IRB or Ethics Committee
- active participation/leadership in local/state nurses association or other organizations that advance the profession
- demonstration of adherence to requirements of human subject protection during all aspects of clinical research

Team Focus and Interprofessional Collaboration – recent or current activities that identify the applicant's involvement in developing a team focus with interprofessional collaboration in the work setting. Accepted activities include but are not limited to the following:

- active participation/leadership in collaborative practice team, Joint Commission/disease-specific certification interprofessional group
- facilitation and implementation of clinical research protocols through interprofessional or research team collaboration

Quality and Safety – recent or current activities that identify the applicant's contribution to quality and safety outcomes in the work setting. Accepted activities include but are not limited to the following:

- active/leadership in quality and safety committees
- participation in quality and safety education

- participation in root cause analysis initiatives
- monitoring of safety of research participants
- monitoring of study integrity and quality of data

Evaluation of each area (per rubrics)

1. Relevance to domain/thoroughness of discussion (substantive response): 4 points
2. Demonstrates higher level of expertise: 4 points
3. Presentation of content (writing clarity, grammar; presentation directions followed): 4 points
4. Reflects best practices in clinical research nursing: 4 points

Please see rubric by section on the following pages to identify how the portfolio reviewers will score the exemplar. A minimum score of 45 points (of 64 possible) is required for an exemplar to be accepted toward certification by portfolio.

Exemplar Rubric

Professional Growth	1 Unacceptable	2 Marginal	3 Good	4 Excellent
Demonstrates higher level of expertise	Degree of expertise unclear from evidence	Minimal demonstration of expertise	Acceptable evidence of high level of expertise	Clear, compelling evidence of higher level of expertise
Relevance to domain/ thoroughness of discussion	Minimal discussion of how identified activities developed the applicant as a professional	Very limited discussion of how identified activities developed the applicant as a professional	Acceptable level of detail in discussion of how identified activities developed the applicant as a professional	Substantive discussion with rich detail of how identified activities developed the applicant as a professional
Reflects best practices in clinical research nursing	Minimal or no evidence of current best practices in clinical research nursing	Very limited evidence of current best practices in clinical research nursing	Acceptable evidence of current best practices in clinical research nursing	Clear, compelling evidence of current best practices in clinical research nursing
Presentation of content*	Poorly written with many errors in grammar, spelling, sentence structure; no apparent attempt to organize content based on directions	Limited clarity in writing with frequent errors in grammar, spelling, sentence structure; all elements of directions addressed but organization lacking	Generally good writing with few errors in grammar, spelling, sentence structure; generally good organization based on directions	Well written with minimal errors in grammar, spelling, sentence structure; well organized based on directions

*Follows directions for presentation; writing clarity, correct use of grammar and spelling

Exemplar Rubric

Professional and Ethical Practice	1 Unacceptable	2 Marginal	3 Good	4 Excellent
Demonstrates higher level of expertise	Degree of expertise unclear from evidence	Minimal demonstration of expertise	Acceptable evidence of high level of expertise	Clear, compelling evidence of higher level of expertise
Relevance to domain/ thoroughness of discussion	Minimal discussion of how identified activities developed the applicant as a professional	Very limited discussion of how identified activities developed the applicant as a professional	Acceptable level of detail in discussion of how identified activities developed the applicant as a professional	Substantive discussion with rich detail of how identified activities developed the applicant as a professional
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*Follows directions for presentation; writing clarity, correct use of grammar and spelling

Exemplar Rubric

Team Focus and Interprofessional Collaboration	1 Unacceptable	2 Marginal	3 Good	4 Excellent
Demonstrates higher level of expertise	Degree of expertise unclear from evidence	Minimal demonstration of expertise	Acceptable evidence of high level of expertise	Clear, compelling evidence of higher level of expertise
Relevance to domain/ thoroughness of discussion	Minimal discussion of how identified activities developed the applicant as a professional	Very limited discussion of how identified activities developed the applicant as a professional	Acceptable level of detail in discussion of how identified activities developed the applicant as a professional	Substantive discussion with rich detail of how identified activities developed the applicant as a professional
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*Follows directions for presentation; writing clarity, correct use of grammar and spelling

Exemplar Rubric

Quality and Safety	1 Unacceptable	2 Marginal	3 Good	4 Excellent
Demonstrates higher level of expertise	Degree of expertise unclear from evidence	Minimal demonstration of expertise	Acceptable evidence of high level of expertise	Clear, compelling evidence of higher level of expertise
Relevance to domain/thoroughness of discussion	Minimal discussion of how identified activities developed the applicant as a professional	Very limited discussion of how identified activities developed the applicant as a professional	Acceptable level of detail in discussion of how identified activities developed the applicant as a professional	Substantive discussion with rich detail of how identified activities developed the applicant as a professional
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*Follows directions for presentation; writing clarity, correct use of grammar and spelling

Area Scores

- Professional Growth _____
- Professional and Ethical Practice _____
- Team Focus and Interprofessional Collaboration _____
- Quality and Safety _____
- **Total Exemplar Score (of possible 64)** _____