Evolution of Clinical Research Nursing

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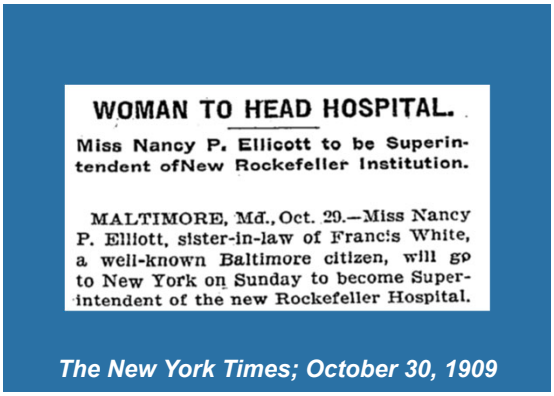
In the Beginning…..

- 1910: Rockefeller Institute Hospital opened as the first center for clinical research in the U.S.
- Founders of Rockefeller Hospital knew that well-educated nurses would be required for a successful research program
- Nancy P. Elliot hired as the superintendent of nursing



WOMAN TO HEAD HOSPITAL.

Miss Nancy P. Ellicott to be Superintendent ofNew Rockefeller Institution.

MALTIMORE, Md., Oct. 29.—Miss Nancy P. Elliott, sister-in-law of Francis White, a well-known Baltimore citizen, will go to New York on Sunday to become Superintendent of the new Rockefeller Hospital.

The New York Times; October 30, 1909

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…In the Beginning

- Elliot's leadership set a high standard for the role of nurses in the new field of clinical research

"In order to make possible the realization of the aspirations of the founders of the hospital, the nursing must be of the very highest type. ***Records must be most carefully and accurately kept, symptoms observed and recorded, reports intelligently and faithfully made, for a lapse in vigilance, or in a specimen lost in a moment of heedlessness, might render worthless the labor of many weeks****."*

The Rockefeller University, n.d.

A Trip Through History: 1960's – 1980's

- 1960's: Chemotherapy clinical trials provided the first roles for oncology nurses in cancer research
  - New skills
  - New knowledge
  - New collaborative role with physicians
- 1980's:
  - Description of the research nurse in cancer research setting
  - Other nursing specialties began to describe emerging role

Hubbard & DeVita, 1976; Moore, 1978; Suppers et al, 1979; Henke, 1980; Hubbard & Donehower, 1980; Hubbard, 1982; Mullin, 1984; Gross, 1986

A Trip Through History:1990's

- Further descriptions of the oncology research nurse role and activities
  - Preparing nursing staff for successful implementation of a protocol
  - Merging role of oncology nurses in data management
  - Identifying research nurse involvement in the informed consent process
  - Identifying research nurse contribution to clinical research
- Literature mostly provided anecdotal evidence

White-Hershey & Nevidjon, 1990; Cassidy & Macfarlane, 1991; Engelking, 1991, 1992; Hazelton, 1991; McEvoy et al, 1991; Melink & Whitacre, 1991; Wheeler, 1991; Cassidy, 1993; Berry et al, 1996; Freedman, 1998; Xanthos et al, 1998; Rosse & Krebs, 1999

The New Millennium

- Emergence of more critical and substantive literature surrounding the role of the research nurse
- Ocker and Pawlik-Plank (2000) used a case study to explain how the research nurse role was systematically developed and integrated into a clinic-based oncology research setting
  - Identified several research nurse roles that incorporated the nursing process: educator, patient advocate, and protocol manager
  - Implementation and integration of the research nurse in their setting led to increased job satisfaction for both research nurses and oncology nurse clinicians
- Burnett et al (2001) surveyed nurses' attitudes and beliefs toward cancer clinical trials at a comprehensive cancer center.

Oncology Nursing Society ….

- 1990: Clinical Trial Nurses Special Interest Group (CTN SIG)
- 2000: CTN SIG published first edition of the *Manual for Clinical Trials Nursing*
  - First comprehensive nursing work that included CTNs from across the globe
    - International section (4 countries)
  - Manual designed to address the needs of the novice CTN while also appealing to the expert CTN
  - 2008: 2nd edition
  - 2016: 3rd edition (16 countries + EU Directive)
  - 2024: 4th edition begins

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…ONS CTN SIG

- CTN SIG developed a valid and reliable tool to assess the role of the research nurse within oncology
  - Clinical Trial Nurse Questionnaire© (CTNQ)
- CTNQ has been validated and used by others to further define the roles and responsibilities of nurses in clinical research in US, Italy, Australia, and Korea

Choi & Park, 2018; Ehrenberger & Lillington, 2004; Catania et al, 2008, 2011; Nagel et al, 2010; Wilkes et al, 2012

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Defining CRN Practice & Competencies

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United Kingdom (U.K.)

- 2004 – 2006: Landmark policy changes to the National Health Services (NHS) in the U.K.
- Research has become a front-line core service of the NHS which led to increasing roles for nurses
- Clinical Research Nurse (CRN)
  - Any nurse who is employed to primarily undertake research in the clinical environment
- 2007: Working Group established to develop a competency framework for the CRN
- December 2008: Competencies published
- October 2011: 2nd edition published
  - Incorporated the leveling of competencies based on band

Royal College of Nursing Research Society, 2011

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U. K. CRN Competencies

- To demonstrate understanding of the background, political influence and strategy regarding clinical research in the UK
- To work within, and adhere to, the requirements of research ethics, research governance and legislation
- To understand, apply and promote the principles and practice of obtaining valid informed consent
- To apply professional knowledge and skills to facilitate efficient, safe and participants focused clinical research

Royal College of Nursing Research Society, 2011

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NIH Clinical Center (CC) Nursing

- 2007: NIH CC nursing department began a 4-year initiative to define and delineate the practice within the specialty of CRN
- Developed a taxonomy for the CRN specialty
- Used a Delphi approach (3 rounds), to develop and validate 5 domains of practice for the CRN
- Identified 52 activities identified within the specialty of the CRN
- Conceptualized 2 distinct roles for nurses practicing in clinical research settings

Castro et al., 2011; Bevans et al., 2011; Hastings et al, 2012

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CRN Domains of Practice & Roles

5 Domains of Practice

- Clinical Practice
- Study Management
- Care Coordination and Continuity
- Human Subject Protection
- Contributing to the Science

2 Roles

- Clinical Research Nurse
  - Role primarily focusing on direct care
- Research Nurse Coordinator (RNC)
  - Role primarily focusing on study coordination

Initially posted on NIH Clinical Center website September 2009

ONS CTN Competency Development…

- 2007: Work group to develop competencies
- Why develop:
  - Great variability in CTN position titles, role implementation
  - Need for role clarification and standardization
  - Need to validate the unique contribution that nurses bring to clinical trials
  - Lack of literature defining the role of the oncology CTN
  - Consistent feedback from the ONS membership, especially the CTN SIG about need for resources

…ONS CTN Competency Development

- 2007: ONS leadership called for the development of clinical trials competencies
- Project Team:
  - Five ONS members currently working in oncology clinical trials
  - Chosen based upon experience with clinical trials and defining competencies/job descriptions in diverse practice settings
  - Mission: To delineate the core values, skills, knowledge, and expertise required to become proficient as an oncology CTN, highlighting the unique contribution that nurses, and the nursing process, bring to clinical trials practice.

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Competency Development Process

- Three step process
  - Initial competency draft
  - Field review
  - Expert review
- Focus on novice CTN

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Expert Review Outcomes

- Reduced Competency Categories to 9
  - Protocol Compliance
  - Clinical Trials-Related Communication
  - Informed Consent Process
  - Management of Clinical Trials Patients
  - Documentation (incorporated Research-Related Technology)
  - Patient Recruitment
  - Ethical Issues
  - Financial Implications
  - Professional Development
- Ended up with a total of 54 competency statements

Lubejko et al, 2010

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2nd Edition OCTN Competencies

- Process started
- Literature review: What's new in the literature since initial competencies (related to nurses in research and competencies)
  - Literature related to levels
  - Literature related to dividing knowledge and behaviors
  - Literature that led to new behaviors/competencies

ONS, 2016

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Review Process

- Revision team decided to use levels
- Minor changes to categories including reorganization
- Developed a model
- Field review
- Expert review
- Final competencies

ONS, 2016

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2010 Competency Categories	2016 Competency Categories
Protocol Compliance	Adherence to Ethical Standards
Clinical Trials-Related Communication	Protocol Compliance
Informed Consent Process	Informed Consent
Management of Clinical Trials Patients	Patient Recruitment and Retention
Documentation	Management of Clinical Trial Patients
Patient Recruitment	Documentation and Document Management
Ethical Issues	Data Management and Information Technology
Financial Implications	Financial Stewardship
Professional Development	Leadership and Professional Development

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Competency Category A: Adherence to Ethical Standards
The oncology clinical trials nurse demonstrates leadership in ensuring adherence to ethical practices during the conduct of clinical trials in order to protect the rights and well-being of patients and the collection of quality data.

Required Knowledge	Level 1 Behaviors	Level 2 Behaviors

• ANA Scope and Standards
• ANA Code of Ethics
• Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
• The Belmont Report
• Definitions
  ○ Research integrity definition
  ○ Research misconduct definition
  ○ Clinical Equipoise
• Conflict of interest regulations and institutional policies
• Federal and state clinical research laws and regulations
• Good Clinical Practice (GCP)
	a. Performs clinical trials duties in accordance with standards of nursing practice and the Code of Ethics.
	b. Promotes ongoing compliance with the key ethical concepts of respect for persons, beneficence, and justice.
	c. Ensures that members of vulnerable and other special needs populations enrolled in clinical trials are identified and that their rights are addressed.
	d. Maintains awareness of what constitutes falsification of data or other research misconduct.
	e. Adheres to federal and institutional requirements for research misconduct reporting.
	f. Adheres to conflict of interest (COI) regulations and institution-specific policies.
		a. Continuously assesses and reports situations that can lead to research misconduct.
		b. Works with PI and/or research program to develop and implement interventions to provide education about misconduct in order to mitigate risk.
		c. Works with PI and/or research program to develop and reinforce a culture which facilitates compliance with reporting research misconduct.

Resources
• ANA Professional Practice Standards
• ANA Code of Ethics
• FDA Regulations:
  ○ Financial Disclosure of Clinical Investigators
• FDA Guidance:
  ○ Financial Disclosure of Clinical Investigators
• HHS Office of Research Integrity
• OHRP YouTube video: Research Involving Vulnerable Subjects
• ONS Manual for Clinical Trials Nursing – 3rd edition, Chapter 12
• Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
• The Belmont Report		

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ONS, 2016

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Competency Update 2024

- Oncology Nursing Society and the Oncology Nursing Certification Corporation Boards of Directors
- Updating the current competencies designed for nurses working in clinical research
- Sought input on the fundamental knowledge, skills, and expertise necessary to excel in this role
- Potential name change from CTN to CRN

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General Clinical Research Center Programs

- 1960: US National Institutes of Health (NIH) funded General Clinical Research Center
- 1989: establishment of the National Association for GCRC Nurse Managers (GCRCNM)
  - Exchange knowledge and ideas
  - Establish nursing standards in clinical research centers
  - Consult, support and advance competences for GCRC Nurse Managers
  - Set standards for CRN education, training and common research procedures
- 2000: GCRCNM group expanded to included CRNs working outside of the GCRCs

ANA, 2016

International Association of Clinical Research Nurses (IACRN)

- GCRC program was replaced in 2006 to the CTSA
- New CTSA Nurse managers and CC nurse leaders established the National Clinical Research Nursing Consortium to advance the specialty of clinical research nursing
- Organized in 2009 by 7 Nurse Managers from the former GCRCs
- First meeting held in Boston, MA

CRN Definition

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.

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CRN Roles

- Clinician
  - Direct care provider
  - CRN study coordinator
  - Advance clinician
- Manager
- Educator
- Advocate
- Regulatory Specialist
- Nurse Scientist

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Principles that Guide Clinical Research Practice

- Safety and self-determination
- Research informed consent
- Fidelity to the research protocol
- Regulatory compliance

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CRN Scope and Standards Practice

- 2016: American Nurses Association (ANA) approved the Scope of Practice and acknowledged the Standards & Associated Competencies
- Scope of Practice:
  - Defines who, what, when, where, why & how of clinical research practice
- Standards of Practice:
  - Describes the art and science of nursing
  - Details the associated competencies for each standard

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Standards of Practice

- 17 Standards divided into two sections:
  - Standards of *Practice* for CRNs
  - Standards of *Professional Performance* for CRNs
- Each standard has associated competencies:
  - Clinical research registered nurse
  - Graduate level-prepared CRN and the APRN (as applicable)

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Standards of Practice for Clinical Research Nursing

1. Assessment	5. Implementation:
2. Diagnosis	5A. Coordination of Care
3. Outcomes Identification	5B. Health Teaching & Health Promotion
4. Planning	6. Evaluation

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Standards of Professional Performance for Clinical Research Nursing

7. Ethics	13. Evidence-Based Practice & Research
8. Culturally Congruent Practice	14. Quality of Practice
9. Communication	15. Professional Practice Evaluation
10. Collaboration	16. Resource Utilization
11. Leadership	17. Environmental Health
12. Eduction	

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Example: Practice Standard

Standard 1. Assessment:
The clinical research registered nurse collects comprehensive data pertinent to the research protocol requirements and the research participant's health and/or situation.

Competencies
The clinical research registered nurse:

- Documents relevant data in a retrievable format, ensuring IRB requirements for research data.
- Recognizes the research participants as the authority on their own health by honoring their care preferences, including their right to participate or withdraw from the research protocol.

ANA, 2016

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Example: Professional Performance Standard

Standard 7. Ethics:
The clinical research registered nurse practices ethically.

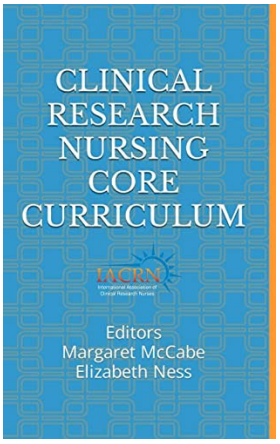
Competencies
The clinical research registered nurse:

- Advocates for the research participants'rights to informed decision-making and self-determination.
- Contributes to the establishment and maintenance of an ethical environment that is conducive to safe, quality health care that maintains fidelity to the research protocol.
- Endorses the understanding that the primary commandment is to the research participant regardless to setting or situation, with a focus on the core principles and guidelines for research involving human subjects.

ANA, 2016

Core Curriculum

- The Evolution of Clinical Research Nursing
- Overview of Clinical Research
- The Ethical Context of Clinical Research
- Protection of Human Subjects
- Protocol Review and Approval
- Informed Consent
- Study Feasibility Assessment
- Recruitment and Retention
- Drug Development Process
- Roles and Responsibilities of the Clinical Research Nurse and Research Team
- Study Conduct and Participant Care
- Data and Safety Monitoring and Reportable Events
- Professional Development for the Clinical Research Nurse



Core Curriculum Update

- 2nd edition underway – expected publication date October 2025
- New chapters:
  - Decentralized clinical trials
  - Digital technology/AI
  - Budget development, billing, and coverage analysis
  - Diversity, Equity and Inclusion in Clinical Research

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IACRN Committees and Chapters

Committees	Chapters
▪ Chapter Governance ▪ Conference Planning ▪ Education ▪ Membership, Marketing and Communication ▪ Nominations ▪ Research	Full Chapters ▪ Beijing China Branch ▪ Boston New England ▪ Japan ▪ New York City ▪ Ohio Valley ▪ Rocky Mountain ▪ United Kingdom/Ireland Pilot Chapters ▪ Africa ▪ Houston ▪ Pennsylvania ▪ Shanghai-China Branch ▪ Southeastern (USA)

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Connecting with IACRN

- IACRN website: https://www.iacrn.org/
- LinkedIn: https://www.linkedin.com/groups/3976821/
- Twitter: https://twitter.com/search?q=iacrn&src=typd
- Facebook: https://www.facebook.com/IACRN/

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Clinical Research Nurse Certification Council

https://www.crncc.org/

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Professional Portfolio Validation of Expertise for Certification

- The CRN-BC™ credential represents the only nursing certification that recognizes expertise as a clinical research nurse.
- Certification will be earned through completion of a professional portfolio that validates the applicant's expert performance in clinical research nursing.

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CRN-BC™ Certification Process

- Complete the Certification Application form
- Complete a minimum number of contact hours of continuing education in clinical research
- Choose at least 2 of 5 professional activity options to document expertise and engagement in the role of clinical research nurse.
- Write an exemplar describing performance and development as an expert CRN in 4 key areas: professional growth, professional practice, team focus and interprofessional collaboration, and quality and safety. (Initial application only)
- Provide a current resume using the template
- Submit your application online

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Documentation of Practice Hours and Licensure

Licensure:

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

Specialty Practice:

- Minimum 4,000 practice hours in the CRN role in the previous 3 years at time of application for certification.

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Continuing Education (CE) Record

- Required CE with **clinical research focus** can be earned *anytime* within the 3 years preceding application for certification by portfolio.
- There is no required number of credits to be earned per year, as long as the total equals *36-50* points/3 years.

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Professional Activities

- Required points can be earned *anytime* within the 5 years preceding application for certification by portfolio.
- There is no required number of points to be earned per year, as long as the total equals *50-64* points/5 years.

Combined points of CE and PD (parts 2 and 3) = 100 pts

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Professional Activities Categories

- Clinical research presentations (e.g. Podium, poster, round tables)
- Scholarly editing & writing (e.g. Research SOPs, journal editor)
- Research & scholarly projects (e.g. CQI/EBP/research)
- Professional activities (e.g. IACRN committee member, preceptor, mentor of novice investigators)
- Academic education

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Exemplar

Exemplar provides evidence of CRN's practice excellence specifically related to:

- Professional growth and Development
- Professional Practice
- Team focus and Interprofessional Collaboration
- Quality and Safety

45 points required with 64 points possible

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Recertification of CRN-BC™

5-year renewal cycle

- Certificants may choose from 2 options:
  - **Option 1:** 75 CEs in 5 years
    Minimum 50 CEs with clinical research focus. The balance in generic nursing CEs to total 75 credits.
  - **Option 2:** A Combination of CEs and Professional Development Points.
    Minimum 50 CEs with clinical research focus. The balance in points earned for professional activities to total 75 credits.
- Both options require **4,000 hours** (less than ½ work-time) of CRN practice in 5 years.
- Recertification Professional Development Activity point system mirrors certification point system.

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Initial Fees & Deadlines

Certification Application Windows and Fees*		
Initial Certification	**Fees**	**Application Window**
IACRN Member	$345	March 1- April 1
		September 1- October 1
Non-IACRN Member	$495	March 1- April 1
		September 1- October 1
*All fees, once paid, are non-refundable and non-transferable		

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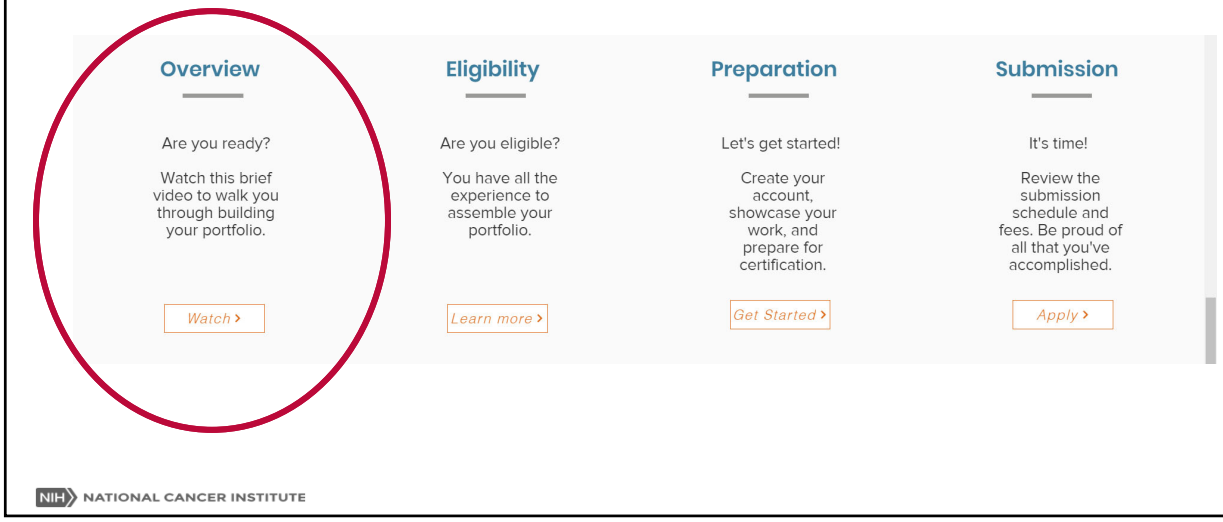

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Summary

- Rich history for clinical research nurses
- Variety of roles
- Variety of settings
- Professional organization
- Core curriculum
- Certification

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References

- Upon request

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www.cancer.gov
www.cancer.gov/espanol

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