
Sheila B. Noone, RN, MPH, PhD
Executive Director,
Dartmouth Clinical & Translational Science Institute
Focus for our discussion:

• Overview of Clinical and Translational Research

• Building capacity at AMCs to support safe, efficient and high value clinical research

• The critical role of the Clinical Research Nurse (CRN): challenges and opportunities for professional development
Clinical Research

• Systematic investigation designed to develop & contribute to generalizable knowledge: *intent is to produce knowledge valuable for understanding human disease, preventing or treating illness, or promoting health*

• Clinical Research embraces a continuum of studies involving interaction with “human subjects,” diagnostic clinical materials or data, or populations such as...

Ref: grants.nih.gov
Clinical Research

• Disease mechanisms
• Clinical knowledge/natural history
• Treatment interventions (clinical trials)
• Prevention/health promotion/behavioral
• Epidemiology
• Community-engaged/health services
• Quality of life

Ref: ncats.nih.gov
Clinical Trial: NIH update 2017

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on a health-related biomedical or behavioral outcome.

**Key questions:**

- Does your study involve human participants (‘subjects’)
- Are the participants prospectively assigned an intervention?
- Is your study designed to evaluate the effects of that intervention on participants?
- Is the effect being evaluated a health-related biomedical or behavioral intervention?
Definition of a ‘human subject’

A *human subject* is defined as a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

Ref: 45CFR46.102 (DHHS)
What is Translational Research?

• The process of *making* and *applying* discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans

• Research aimed at enhancing the *adoption of best practices* in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Ref: ncats.nih.gov
Translational Research

Basic Science
Laboratory discovery and preclinical research

Clinical Research
Human clinical trials

Clinical Medicine
Adopting best practices in the clinic

Observations in clinical practice may lead back to new basic science or clinical research studies.
Clinical & Translational Science Awards (CTSA): NIH push to *discover, develop, disseminate*

- Consortium of over 60 institutions who have received NIH awards to *build institutional capacity* for translational research; preparing next generation of researchers *and* research teams
- National funding began in 2006
- Targeted key areas for infrastructure support and development of core facilities – *mission has evolved*
- Dartmouth College received the CTSA award Oct 2013

More information: [https://ncats.nih.gov/ctsa/about](https://ncats.nih.gov/ctsa/about)
National CTSA Program: 6 in New England
Why is clinical research important?

Gain insights and understanding of:

• Prevention of illness and disease
• Improved diagnostics and treatment of injury and disease
  • Harness technology and improve techniques
  • Manage side effects of accepted treatments
• Wellness/lifestyle, nutrition, behavior
• The burden of illness and disability
Impact on nursing

What has your experience been in supporting, identifying or consenting patients who may be eligible for clinical trials?

Do you feel prepared to care for a patient who is also a participant (‘subject’) in a clinical trial?
The Therapeutic Misconception

• The belief that the purpose of a clinical trial is to benefit the individual patient rather than to gather data for the purpose of contributing to scientific knowledge

• How can we reinforce the distinction between SOC and research?
Building capacity for clinical research

- **Engagement** across the domains of clinical care and clinical trials: team building

- **Research visibility**: patients have to know a clinical trial is an option, and understand their rights

- Investigators (PIs) and all research professionals need **training in Good Clinical (Research) Practice**

- Institution must ensure that **study conduct adheres to GCP** and that **study initiation is efficient**!

- **Patients are waiting**...
Good Clinical Practice (GCP)

- Refers to international ethical and scientific quality standards for designing, conducting, monitoring, recording, analyzing and reporting trials that involve human participants

- Main purpose: **protect human participants** during clinical studies and **protect patients** who might receive approved products in the future
If GCP standards are ignored...

- Participants/patients are put at risk
- Research results are questioned or not accepted
- Future collaborations are put at risk
- Government sponsor restricts funds
- Industry sponsor refuses payment
- If FDA regulated, warning letter could be issued
- All human research can be suspended by FDA or OHRP
Clinical Research Nursing*

• Specialized nursing practice focused on maintaining the equilibrium between care of the research participant and fidelity to the research protocol

• Incorporates GCP and human research protection standards, care coordination, contribution to clinical science, clinical practice and study management

*Clinical Research Nursing: Scope and Standards of Practice (publication of ANA and IACRN)
Clinical Research Nurse (CRN)

- Professional recognition in 2016!
- August 2016 – American Nurses Association (ANA) Board of Directors now recognizes clinical research nursing as a specialty nursing practice...the scope of practice statement for clinical research nursing was approved; the standards of practice have been acknowledged
Domains of CRN Practice: NIH Clinical Research Center
CRN Domains of Practice found within guidance and regulations

- Federal, state regulations & guidance
- Institutional policies and SOPs
  - Credentialing?
  - Certification?

Standards at many institutions are not clearly articulated for CRNs or other research professionals; *hiring, training, and oversight are often decentralized and inadequate*. 

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Evolution of CRN role

• Rich opportunities for nurses to specialize in clinical research nursing:
  • Early phase clinical trials
  • Supporting the *informed consent process*
  • Complex clinical studies or complex medical record extraction
  • Community engagement in hard-to-reach populations
Characteristics of CRNs

• Nurses as patient advocates – CRNs as research participant advocates
  • Support voluntariness of participation
  • Recognize coercion or undue influence when observing research discussions
  • Understand that gaining ‘informed consent’ for research participation is a process (not a one-and-done conversation)
CRNs...

- **Nurses understand the critical importance of data integrity**
  - Accuracy and consistency; RNs support careful and timely documentation
  - Recognize adverse events – record details, report appropriately and ensure proper follow-up
  - Bridge between patient/family, investigator, and sponsor or funder of the study
Challenges to CRN role
Challenges to CRN role...

• Institutional issues:
  • Lack of relevant role descriptions
    • Lack of defined career ladder
  • Lack of distinction between research assistant/non-nurse coordinator and CRN role
  • Lack of credentialing and certification standards
  • May lack relevant standard operating procedures (SOPs) for complex, CRN-managed trials
  • Salary equity with clinical nurses

• Recognition in nursing education programs?
Opportunities for CRN role development

- Find colleagues – CRN role can be isolating!
  - Initiate a CRN Special Interest Group in your institution
  - Educate your clinical colleagues about the value of clinical research and trials
  - Educate the wider community about the value of clinical research
- Join research professional organization
  - IACRN (regional chapter)
  - Seek out certifications in your specialty area
Resources for professional development

• International Association of Clinical Research Nurse (IACRN) [http://iacrn.org](http://iacrn.org)
  • October 2019 – Philadelphia annual meeting

• NIH Clinical Research Center
  [https://clinicalcenter.nih.gov/nursing](https://clinicalcenter.nih.gov/nursing)

• Society of Clinical Research Associates (SoCRA) [www.socra.org](http://www.socra.org)

• Association of Clinical Research Professionals (ACRP) [www.acrpnnet.org](http://www.acrpnnet.org)
Thank you!

Contact information:

Sheila B. Noone
sheila.b.noone@dartmouth.edu
603-650-1878