

“Preparing Nurses to Care for Patients in Clinical Research Projects”



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The College of
St. Scholastica

Objectives

- Describe the importance of federal laws/regulations and ethical principles to advance optimal health care and to promote clinical research.
- Outline how to prepare nurses-- students and staff-- to care for participants in clinical research projects in a variety of settings.
- Identify global resources and organizations to help nurses advance positive health outcomes through clinical research opportunities.
- Thank You: ***Theta Xi*** chapter, **SIGMA**
– Nursing Excellence Award, donation
- Disclosure: No relevant or financial interests related to this presentation.



Theta Xi Chapter

Introduction

- Research as the foundation of evidence-based nursing practice [evidence-informed]
 - Subject in U. S. curricula since ~1970s—steps of process, how to conduct; how to put it into practice
 - Nurse’s attitudes toward research!
 - What’s happening in your country, and nursing curricula today???
- Clinical research—its relationship to nursing—practice, education, professionalism/roles
- Caring for research participants—ethical, legal, professional perspectives
- Why this topic is so important to me.....



Clinical Research



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- **Definition**—varies across the globe
 - *Human* participants
 - Assigned to an *intervention*
 - Designed to *evaluate the effect* of an intervention on the participant
 - *Health-related* biomedical or behavioral outcome
- **Trends**
 - Becoming more complex
 - More prevalent around the world
 - Expanding from individuals to communities

Clinical Research and Trials Lead to Standard Care and Treatment

- **“Carlton man participates in clinical trial that has changed leukemia treatment”**
 - *Duluth News-Tribune*, 29 January 2019
- **“FDA permits marketing of first medical device for relief of pain associated with irritable bowel syndrome in patients 11-18 years of age”**
 - FDA News Release, June 07, 2019
-  Human participant research is governed by laws/regulations, guidelines, and ethical codes

Standards and Regulations

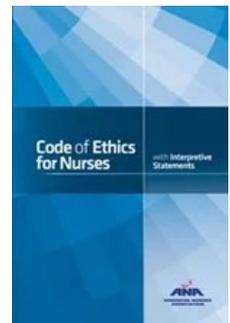
- **National and International Laws**
- **“International Compilation of Human Research Standards”**
(U. S. DHHS, OHRP, 2019)
 - “listings of over 1,000 laws, regulations, and guidelines on human subject protections in 131 countries and from many international organizations”
- **“International Clinical Trials Registry Platform (ICTRP)”** (WHO, 2018)
- **Example of Regulations**—Role of the Institutional Review Board (IRB) and Independent Ethics Committee (IEC); Research Ethics Board (REB) [Canada]
 - U. S. “Common Rule” [revised/implemented 2019]



Ethical Aspects of Research



- Universal Aspects
 - Nuremberg Code, Declaration of Helsinki, Belmont Report, etc.
- “Code of Ethics for Nurses with Interpretive Statements” (ANA, 2015)
 - Nursing Care—safe and ethical practice
 - Respect, beneficence, justice
 - Provision 3: “The nurse promotes, advocates for, and protects the rights, health, and safety of the patient.”
 - 3.2—Protection of Human Participants in Research
 - Principles of respect for autonomy, respect for persons, respect for self-determination
- WHO—Research Ethics Review Committee



Ethical Aspects—“Code of Ethics”

- Provision 7: “The nurse, in all roles and settings, advances the profession through research and scholarly inquiry, professional standards development, and the generation of both nursing and health policy.”
- 7.1—Contributions through Research and Scholarly Inquiry
 - All nurses—Knowledge development, research utilization and evidence-informed practice
 - Commitment to patients/participants—as data collector, investigator, member of an institutional review board or care provider, etc.
 - Nurse executives and administrators—develop structure and processes to create infrastructure and climate conducive to scholarly inquiry.
 - Nurse educators—teach moral standards that guide the profession in the conduct and dissemination of research

Clinical Research/Trials

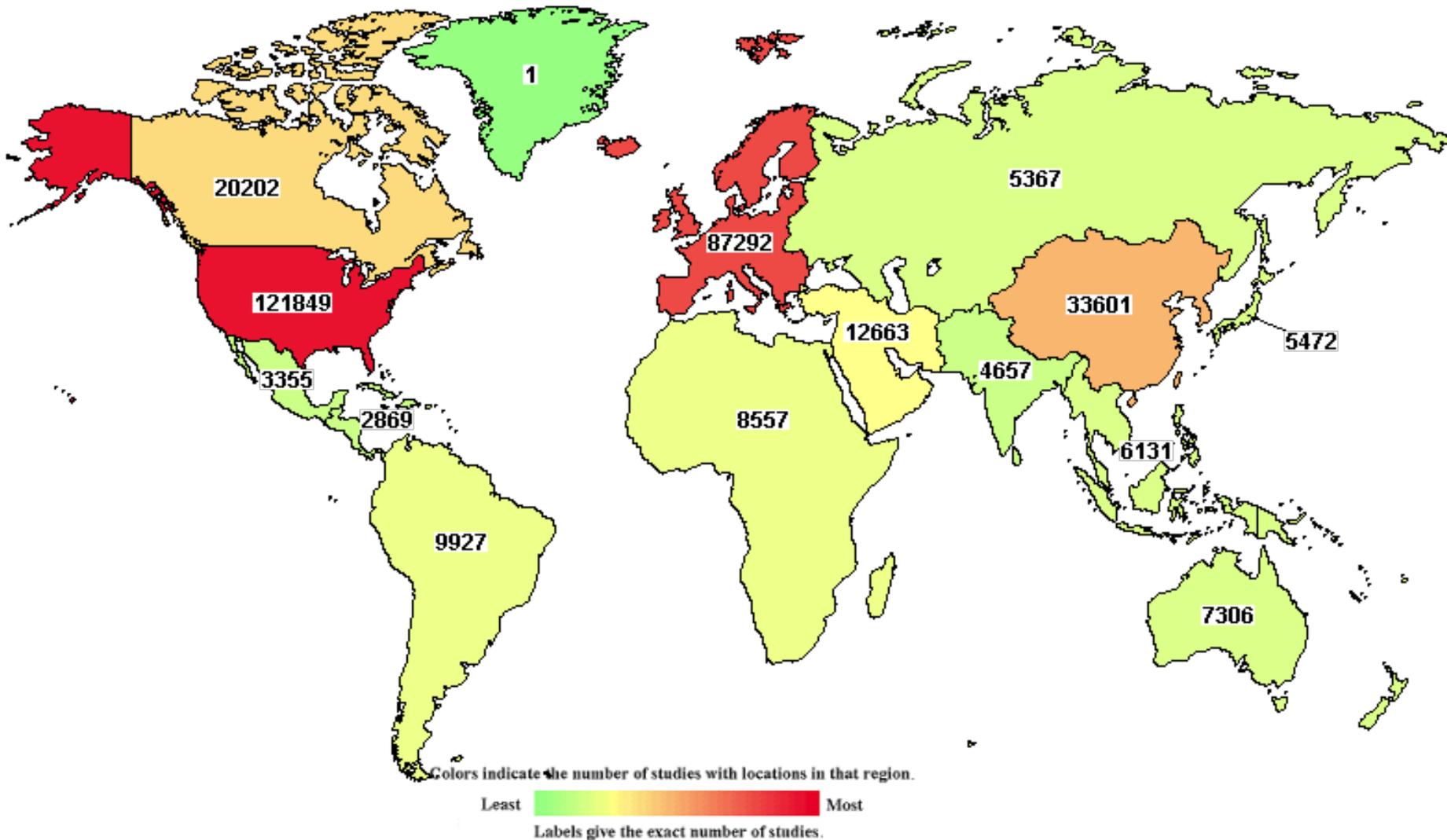
- ***ClinicalTrials.gov***
 - Database of privately and publicly funded clinical studies conducted around the world
 - Provided by U. S. National Library of Medicine (NLM), National Institute of Health (NIH)
- **“Explore 307,343 research studies in all 50 states and in 210 countries.”** [as of January, 2019]

 U.S. National Library of Medicine

ClinicalTrials.gov

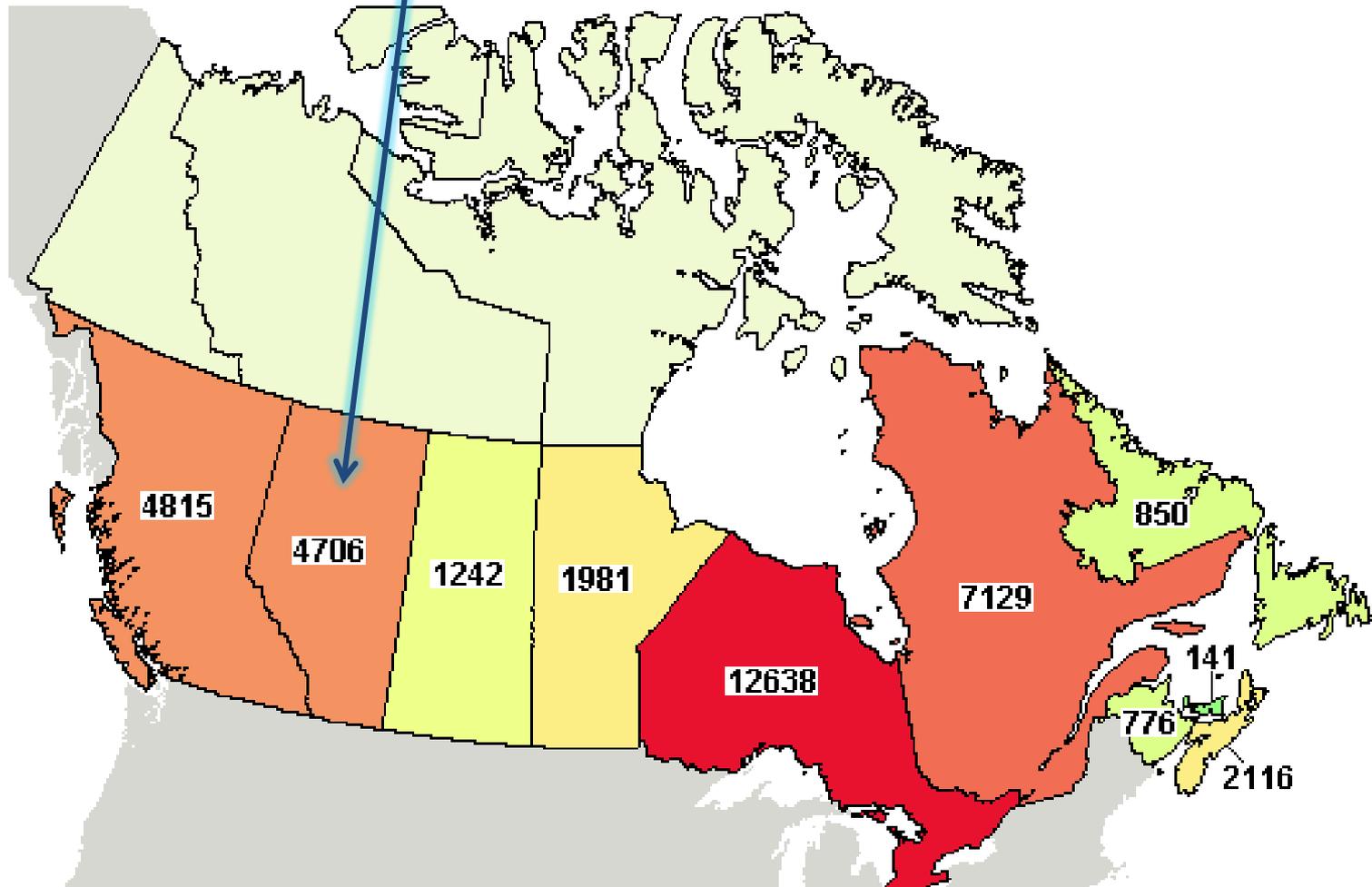
ClinicalTrials.gov

U. S. National Library of Medicine



Canada—registered clinical trials

(clinicaltrials.gov)



Clinical Trial—example

[clinicaltrials.gov]

- Trials could be preventive, diagnostic, screening, quality of life, treatment

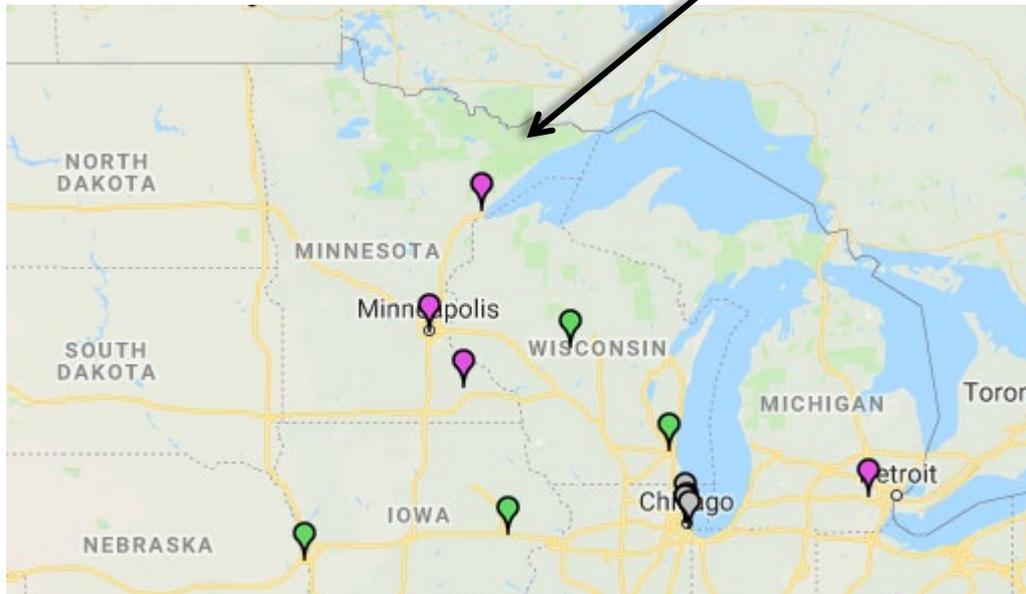
Status	Study Title	Conditions	Interventions	Locations
Not yet recruiting	A Study to Desensitize Allergic Reactions to Treatments for Blood Disorders	<ul style="list-style-type: none">• Multiple Myeloma• Amyloidosis	<ul style="list-style-type: none">• Drug: Lenalidomide• Drug: Pomalidomide	<ul style="list-style-type: none">• Princess Margaret Cancer CentreToronto, Ontario, Canada

Community-Based Research



The National Patient-Centered
Clinical Research Network

The ADAPTABLE study will enroll and follow as many as 15,000 patients with heart disease. Eligible participants in ADAPTABLE will be identified from large health systems that are part of PCORnet's Clinical Data Research Networks (CDRNs). Check out the below map to see if there is an ADAPTABLE site in your area.



THE QUESTION:

Clinicians often prescribe aspirin to prevent strokes and heart attacks in people living with heart disease. Research has yet to determine the best dose to use, since aspirin can cause serious side effects—like bleeding—in some people.

“Effectiveness of a Medication Wallet Card”

- ClinicalTrials.gov Identifier: NCT02820129
- Principal Investigator: Ainsley Moore, MD
- Sponsor: McMaster University

STUDY DRUG INFORMATION WALLET CARD

You are enrolled on a clinical trial using the experimental study drug **rucaparib**. This clinical trial is sponsored by the NCI. Rucaparib may interact with drugs that are processed by your liver, or use certain transport proteins in your body. Because of this, it is very important to:

- Tell your doctors if you stop taking any medicines or if you start taking any new medicines.
- Tell all your health care providers (doctors, physician assistants, nurse practitioners, or pharmacists) that you are taking part in a clinical trial.
- Check with your doctor or pharmacist whenever you need to use an over-the-counter medicine or herbal supplement.

- Rucaparib interacts with specific liver enzymes called CYP1A2, CYP2C9/19, and CYP3A, transport proteins (BCRP, MATE1/2-K, and OCT1) and must be used very carefully with medicines that require these enzymes and transport proteins.
- Before you enroll onto the clinical trial, your study doctor will work with your regular health care providers to review any medicines and herbal supplements that are considered substrates of CYP1A2, CYP2C9/19, and CYP3A, and substrates of BCRP, MATE1/2-K, and OCT1.
- Before prescribing new medicines, your regular health care providers should go to [a frequently-updated medical reference](#) for a list of drugs to avoid, or contact your study doctor.
- Your study doctor's name is _____

and can be contacted at _____.

Role of the Clinical Nurse (Ward-based, Point-of-Care) Related to Clinical Research

- ***Caregiver***—patient, family
- ***Patient Advocate***
- ***Collaborator***—with the Research Team
- ***Professional Activities***



Clinical Nurse as Caregiver

—patient, family



- **How do you identify participants:**
 - Ask: “Are you enrolled in a clinical study?”
 - What electronic/printed system information is available to clinical staff?
- **Answer participant’s/family’s questions**
- **Enrollment/recruitment opportunities—**
access information about available studies
- **Ongoing education:** Protocol/study information; organization policies

Clinical Nurse as Patient Advocate

- **On-the-Job Training**
- **Informed consent process**, e.g. does the participant understand the study?
- **Data collection**—what is critical to know; e.g. what foods to avoid, side effects of treatment?
- **How do you balance protocol requirements with patient care needs**, e.g. risk vs. benefit?
- **Be aware of problems, in order to avoid them!**

Collaborator with the Research Team

- **When/whom to call?** The principal investigator, sub-investigators; nurse coordinator, research nurse, data manager, infusion nurse, etc.
 - Laboratory, Radiology, Pharmacy
- **How to report adverse events**
- **How to support the research team**

Professional Activities of the Clinical Nurse:

- **Continuing Education;**

e.g. look for work by Elizabeth Ness, MS, BSN, RN; Nurse Consultant, Education Center for Cancer Research, NCI

- **Committee and Institutional Work**

- Healthcare committees

- Institutional Review Board (IRB); e.g.

- Research Ethics Board (REB) Canada

- Swedish Ethical Review Authority



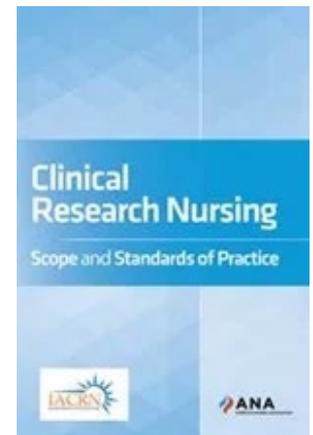
- **Advanced Education—Clinical Research Nurse Role?**

Nursing Education & Clinical Research

- **Discussing Research-- Training/Learning**
 - Scientific process—what do nurses need to know?
 - Educational levels—where to teach content; certification?
- **Research-related Issues; e.g. attitude**
- **Collaboration/Partnerships**
 - American Association of Colleges of Nursing (AACN)
 - **Recommendation #5** Invest in Nursing Research Programs and Better Integrate Research into Clinical Practice
 - Strengthen Clinical Research Nursing through growth and development of programs to support nurse clinical trial coordinators and clinical research nurses.

Nursing's Future Involvement with Clinical Research

- **Emerging Role of the Clinical Research Nurse (CRN); Clinical Trials Nurse (CTN)**
 - Education; Certification
 - “Clinical Research Nursing: Scope and Standards of Practice” (2016)
 - Scope of practice varies throughout the globe
 - Professional Organizations—see next slide



Professional Groups

– Professional Organizations

- International Association of Clinical Research Nurses (IACRN)
- UK Clinical Research Collaboration (UKCRC)
- Association of Clinical Research Professionals (ACRP)
- Society of Clinical Research Associates (SOCRA)



Management and Organizational Involvement

- Organizational Self-Assessment
 - Clinical Research Goals; workplace culture
- Advanced educational opportunities
 - e.g. Scholar-in-residence (Jeffs, 2015)
 - Resources available for staff
- Organizational Roles and Opportunities
 - Hospitals, Clinics, Universities, etc.
 - Professional Groups

Next Steps!

- Set a learning agenda for yourself to understand more about clinical research participation, its legal/regulatory aspects, and its ethical components.
- Create ways to interact effectively with participants and clinical research staff, to promote nursing's goal of safe, ethical practice .
- Discover useful resources related to clinical research that you can incorporate into your professional role and development.



- Thank you, everyone!



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- Questions?



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Country-specific

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“Clinical Trials Nursing Questionnaire,” done in various countries to look at clinical trials nursing role; Sweden, Korea, Australia, Italy

<http://allie.dbcls.jp/pair/CTNQ;Clinical+Trials+Nursing+Questionnaire.html>

Informational Websites

Centerwatch <https://www.centerwatch.com/>

International aspects related to human research

<https://www.hhs.gov/ohrp/international>

“Nursing Research” from the American Nurses Association. Use this as an example of what may be available from your nursing organization

[https://www.nursingworld.org/practice-policy/innovation/im\(proving-your-practice/research-toolkit/](https://www.nursingworld.org/practice-policy/innovation/im(proving-your-practice/research-toolkit/)

SACHRP Committee (Secretary’s Advisory Committee on Human Research Protections) <https://www.hhs.gov/ohrp/sachrp-committee/index.html>