Clinical and Translational Research: The Future is Bright

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What is Clinical and Translational Research?

The application of discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in human subjects and investigations of strategies to enhance the adoption of best clinical practices in the community.
What is Needed for Success?

- Strong, broad scientific base
- Resources
- Opportunities
- Mentor(s)
- Access to additional education and training
- Curiosity
- Enthusiasm
- Perseverance
- Understanding – it is a long journey
A Journey

• Medical school
  – Traditional curriculum (2 years pre-clinical, 2 years clinical)
  – Offered opportunity to do research – worked with neurologists on pathogenesis of brain abscess and mycotic aneurysm (dogs)
  – Research award in 3rd year
  – Two publications in Neurology in 4th year
  – Graduated with “Distinction in Research”
A Journey

• Residency – Internal Medicine
  – Focused on patient care in research intensive institution
  – Little time for research, but patient care identified many unanswered questions

• Fellowship – Pulmonary
  – Plan – become a clinician
  – Year 1 – clinical, chose mentor for research in year 2
  – Plan – pulmonary immunology, but faculty member left
  – What to do?
A Journey

- Recommendation – work with best researcher
- Research
  - Pulmonary alveolar type 2 cells in mice
  - Studied response to injury; developed new method to monitor cell division and transition to type 1 cells
  - Took long time to get publishable data
- Took 3rd fellowship year to continue research and consider career in academia
A Journey

- Faculty Position
  - Where to go?
  - Factors?
    - Work environment – people, resources, etc.
    - Family/Location
    - Finances – salary, debt
  - Family issues key → Chicago → NU
- What has happened since coming to NU in 1979?
A Journey

- Junior faculty member – 75% research, 25% clinical
- Applied for research grants
  - Continued and expanded work done during fellowship
  - Acute lung injury/ARDS – funded by VA
- Pulmonary Division chief after 3 years on faculty
- Offered opportunity to do clinical research component of asthma translational research project – leukotrienes
A Journey

- For 10+ years did both mouse and clinical research (two different areas, some overlap)
- Gradually shifted to solely asthma clinical research (mechanism-based studies and clinical trials) – funded by industry and NIH
- 15 years ago – Chicago PI of new ALA-ACRC network
- 6 years ago – Chicago co-PI of NHLBI AsthmaNet
A Journey

• Along the way – locally
  – IRB Chair, multiple FSM committees
  – Founded MSCI program (16 years ago)
  – Associate VP for Research (11 years ago)
  – NUCATS
    • Co-director – Center for Education and Career Development
    • Director – Center for Clinical Research
A Journey

• Along the way – nationally
  – Consultant to industry – novel asthma treatments
  – NIH grant review committees
    • *Ad hoc review committees*
    • NHLBI K23/24/25 – now chair
  – External advisory board of CTSA programs – U of Wisconsin, UNC
A Journey – Nearly Complete

• For a physician researcher – contact with patients and exposure to both bench (translational) and clinical research provide a unique perspective
• Learn as much as possible from others
• Medicine and biomedical research have changed greatly over the last several decades; will continue to change at increasing speed
• There continue to be unlimited opportunities
You Made It
How Can We Help You on Your Journey?
Northwestern University Clinical and Translational Sciences Institute (NUCATS)

**Mission:** To speed transformative research discoveries to patients and the community

**Goal:** Promote Northwestern's culture of collaboration, innovation and translation through team-building, education, and training to empower the multidisciplinary translational research teams of tomorrow.

*Provide the infrastructure that makes it easy for researchers to find and utilize the available resources and services at NU.*
NUCATS Services

- Preclinical Discovery
- Center for Clinical Research
- Biomedical Informatics
- Quantitative Methods Group
- Education and Career Development
- Community Engagement/Population Health Services
- Galter Health Sciences Library
Preclinical Discovery

- Funding opportunities through Office of Research Development (ORD)
- Information on pilot funding opportunities across NU
- Support new drug and device development
Center for Clinical Research

- Study budget development/negotiation
- IRB, IND, IDE submission support
- Research participant recruitment assistance
- Nurse and non-nurse clinical research coordinators
- Clinical Research Unit (CRU) at NMH and LCH for inpatient and outpatient visits
  - Space
  - Research nursing services
  - Bionutrition (e.g., controlled diets)
  - Core laboratory – specimen preparation and assays
Biomedical Informatics Services

- Secure, web-based applications for studies
  - REDCap (Research Electronic Data Capture) – data collection forms
  - eNOTIS – study enrollment log; required for all individuals enrolled in clinical trials using services at NMHC and NMG
  - RegiStar – research subject registry system

- Northwestern Medicine Enterprise Data Warehouse (NMEDW)
  - Houses clinical and research data on all patients receiving care at NU clinical affiliates
Quantitative Methods Group

- Biostatistics, bioinformatics, epidemiological, programming, and data management support
Education and Career Development

- Master of Science in Clinical Investigation (MSCI)
- Master of Science in Regulatory Compliance (MSRC)
- Non-credit training, seminars and workshops to on-board new faculty and staff including Clinical Research Coordinator (CRC) Basic Training, Basics of Clinical Research
- Responsible Conduct of Research Training (required by NIH and other federal agencies)
- Training grant writing support (T, K, F awards and resources)
Community Engagement/Population Health Services

- Consultations for design and implementation of projects that include stakeholder engagement
- Research proposal review and support
- Partnership brokering and development for community-academic research teams
- Funding opportunities (including seed grants)
Gal ter Health Sciences Library

- Literature and systematic review searches and bioinformatics collaboration/support
- Training in software, databases and bioinformatics tools:
  - EndNote – bibliographic management program
  - PubMed
  - National Center for Biotechnology Information (NCBI) tools
Research Navigators

– Central points of contact across the University
– Assist investigators in navigating the clinical and translational resources available at NU and at our collaborators

NUCATS – central phone: 312-503-1709
email: nucats@northwestern.edu
Questions?
Supplemental Material
Clinical/Translational Research

Resources and services -

• Office for Research
  – Regulatory functions
  – Centers
  – Core facilities
• School Based – centers and cores
• NUCATS – services (already covered)
Resources and Services

- IRB Office (Institutional Review Board) – humans
- IACUC (Institutional Animal Care and Use Committee) – animals
- CCM (Center for Comparative Medicine) - animals
- IBC (Institutional Biosafety Committee)
- OSR (Sponsored Research)
- ORS (Research Safety)
- INVO (Innovation and New Ventures)
- ORD (Research Development)
- ORI (Research Integrity)
IRB Office - Humans

• Reviews and approves research projects involving human subjects or identifiable private information obtained from human subjects.
• Assists investigators in planning and conducting experiments in accord with the highest scientific, humane, and ethical principles and in conformity with relevant laws, regulations, and policies.
• Liaison between investigators and the federal government.
• Safeguards rights and welfare of human subjects.
IACUC - Animals

• Reviews and approves all new animal study protocols (ASP), annual certifications, and addenda
• Assists investigators in planning and conducting experiments in accord with the highest scientific, humane, and ethical principles and in conformity with relevant laws, regulations, and policies
• Liaison between investigators and the federal government
• Safeguards rights and welfare of animal subjects
Center for Comparative Medicine (CCM)

- Veterinary staff, technicians and animal caretakers
- ~100 employees
- Primary care and oversight of vertebrate animals used in research
- Surgery; training
- Facilities in Chicago and Evanston
- Large and small animals
Office for Sponsored Research: Grants and Contracts

- Assists in proposal development
- Reviews and endorses proposals
- Negotiates agreements
- Accepts and appropriates awards
- Interprets guidelines and promotes compliance with sponsor (government, foundations, industry) and University policies
Office for Research Safety

- Develops, implements, and coordinates the chemical, biological, radiation, and general laboratory safety programs for the University for hazardous chemicals, sources of radiation, and human blood or other potentially infectious human materials
- Assures University compliance with federal, state, and local regulations
- Institutional Biosafety Committee (IBC; aka – recombinant DNA committee)
Innovation and New Ventures - INVO

- Facilitates commercialization of University's innovative technologies for public use and benefit
- Protects the inventors' and University's rights in novel technologies, copyrights, and software
- Markets technologies to industry and investors
- Provides coaching and networking to create start-up companies (for profit or non-profit) based on University innovations that benefit society
- Structures and negotiates license agreements
Office of Accounting Services for Research and Sponsored Programs

- ASRSP
- Financial reporting, invoicing, collecting revenue, coordinating audits and processing transactions
- Effort reporting
- Equipment
OR Research Centers

• Argonne/NU Solar Energy Research Center
• Center for Cancer Nanotechnology Excellence
• Center for Catalysis and Surface Science
• Chemistry of Life Processes Institute
• Center for Molecular Innovation and Drug Discovery
• Center for Reproductive Sciences
• Center for Sleep and Circadian Biology
• Institute for Bionanotechnology in Medicine
OR Research Centers

- Initiative for Sustainability and Energy at Northwestern
- Materials Research Center
- Northwestern Institute on Complex Systems (NICO)
- NU Atomic and Nanoscale Characterization Experimental Center (Core)
- Nanoscale Science and Engineering Center
- Physical Sciences Oncology Center
FSM Research Centers

• Center for Genetic Medicine/NUGene
• Institute for Healthcare Studies
• Institute for Women’s Health Research
• Interdepartmental Immunobiology Center
• Robert H Lurie Comprehensive Cancer Center
• Center for Communication and Medicine
• Cognitive Neurology and Alzheimer’s Disease Center
• Feinberg Cardiovascular Research Institute
• NM Developmental Therapeutics Institute
Research Cores

• Advanced Photon Source (DND- and LS-CAT) – structural biology
• Behavioral Phenotyping core
• Bioethics Consultation and Research Core
• Biostatistics Collaboration Center
• Cell Imaging Facility
• Center for Advanced Magnetic Resonance Imaging
Research Cores

• Center for Advanced Molecular Imaging
• Clinical Pharmacology Core
• Flow Cytometry Facilities
• Gene Chip and Microarray Facility
• Genomics Core Facility
• High Speed Cell Sorter
• High Throughput Analysis Lab
• Stem Cell Facilities
Research Cores

• Monoclonal Antibody Facility
• Outcomes Measurement and Survey Core
• Pathology Core
• Proteomics Center of Excellence
• Research Histology Core
• Transgenic and Targeted Mutagenesis Core