Translational Science Spectrum

https://ncats.nih.gov/translation/spectrum
ICTS Overview

1. Workforce Development
2. Biomedical Informatics
3. Research Methods
4. Community and Collaboration
5. Clinical Research Support
6. Translational Pilot Program
Core Professional Development and Education Activities

Undergrad Students → Research Coordinators → T Program (Post-Docs) → K Program (Junior Faculty) → Faculty → Community

Translational Science Navigator
Mentor Training and Development
Team Science

CTS Certificate
GCP
EPIC
New to CR

Masters in Translational Biomedicine
- Biostatistics
- Epidemiology
- Study Design
- Funding Process
- Commercialization
- Scientific Writing
- Clinical Research Ethics
- Presentation Skills

K Club
Specific Aims Class
Presentation Skills Class
Significance & Innovation Class
Funding Opportunities Class
Mock Study Sections
Mock IRB Sessions
Comparative Effectiveness
PCORI Workshop
Rigor and Reproducibility Class
Good Clinical Practice for PIs
Community Engagement
Undergraduate Mentoring

Outcome: First Author Publication or Draft of a Grant

Mentor Academy
Clinical Lecture Series
Team Science Training
Specific Aims Class
PCORI Workshop
Good Clinical Practice for PIs

Outcome: NIH K Award or R01 (or equivalent)

ICTS Professional Development / Education Activities

Mentor Academy
Clinical Lecture Series
Team Science Training
Specific Aims Class
PCORI Workshop
Good Clinical Practice for PIs

Undergrad Students → Research Coordinators → T Program → K Program → Faculty → Community

ICTS Institute for Clinical & Translational Science
AT THE UNIVERSITY OF IOWA
Core Professional Development and Education Activities

MASTER OF SCIENCE IN TRANSLATIONAL BIOMEDICINE DEGREE PROGRAM
- Intro to TBM Course
- Critical Thinking Series
- Epidemiology I
- Intro to Biostatistics
- Clinical Research Ethics
- Research Electives

KL2 PROGRAM
- Mentored Research and Funding
- NRMN Mentor and Mentee Training
- R01 Boot Camp
- Translational Science Navigator for IDP Development
- K Club

TBM NON-CREDIT CAREER DEVELOPMENT ACTIVITIES
- Workshops (CER, PCOR, Specific Aims, Innovation, Funding, Networking)
- Seminars (Scientific Communication Skills, Community Engagement, Entrepreneurship)
- Trainings (Team Science, Mentor and Mentee, GCP)
Clinical Research Unit

- Inpatient and outpatient
- 20,000 sq ft
  - 16 examination rooms
  - 6 consultation rooms
  - 3 procedure room
  - 7-bed infusion suite
  - A conference room & work stations

- Specific facilities for
  - Pediatric, oncology, bariatric, and neuroscience studies
  - Metabolic research kitchen and dining facility
  - Pulmonary function, vascular physiology, and body composition labs
Clinical Research Resources—Goals

• Provide unique resources to:
  – Enable high quality clinical research
  – Support the recruitment of new faculty interested in clinical research
  – Support the career development of early-stage clinical and translational investigators

• Promote interactions between basic and clinical research faculty and the translation of laboratory discoveries to humans.
Clinical Research Resources

- Inpatient/Outpatient Studies
- Procedural Support: bronchoscopy, biopsies
- Infusions: Biologic agents and chemotherapy
- Specialized Labs: Pulmonary function, Vascular Imaging
- Sample Processing
- Unique satellite unit in College of Dentistry

- Regulatory Support
- Study Planning
- Subject Recruitment
- Data Management
- Off-site encounters

- Pediatric Expertise
- Neonatal Intensive Care Unit
- Study Coordination
Clinical Research Resources

• 100 new protocols annually; >200 protocols currently open

• Investigators from UI College of Medicine, Public Health, Pharmacy, Nursing, Dentistry, Liberal Arts, Law, Engineering, Education, and Business

• Sponsors include NIH, Veterans Affairs, Foundations, Pharmaceutical/Device Industry, and Internal funds.
Clinical Research & Trial Readiness

- Clinical Research Professional Training Academy
  - Goal: increase pool of trained clinical research personnel; enhance skills of coordinators
  - Audience: newly hired clinical research staff; health care providers with research interest (RNs, RRTs, etc); laboratory research staff with clinical research interest; individuals outside healthcare and research fields
  - First offered October, 2016
Identify Modules Needed

Joint Task Force for Clinical Trial Competence, 2014

ICTS Institute for Clinical & Translational Science AT THE UNIVERSITY OF IOWA
Clinical Research Professional Training Academy Curriculum

DAY 1
A. Welcome, Introductions
   A. Overview and Objectives
B. Navigating the IRB Review Process for Human Subjects Research
C. Informed Consent: History, Regulations, and Best Practices
D. Human Research Protection Program (HRPP) Committees and Units Panel Discussion:
   i. Protocol Review and Monitoring
   ii. Pharmacy & Therapeutics
   iii. Nursing Research
   iv. Medical Radiation Protection
E. Division of Sponsored Programs: Who Are We and how Do We Impact Clinical Trials?

DAY 2
A. Financial Conflicts of Interest in Research: What You Need to Know
B. ClinicalTrials.gov PRS – How to Register and Maintain and Record
C. Study Start-Up: The Treasure Map
D. Budgeting, Policy on Documentation of Patient Participation, ICON Requirement, and I-CART
E. Research Billing Compliance

DAY 3
A. Documentation
B. Safety of the Subject
C. REDCap Overview
D. UI BioShare: University of Iowa’s Biomaterial Data Management System & Research Service
E. TriNetX
F. EPIC Tools for Clinical Research
Clinical Research Professional Training Academy Curriculum

Additional Training Available

A. Introduction to Clinical Research Unit
   A. CRU orientation for new coordinators
   B. Policies and Procedures for CRU Utilization
   C. Tour

B. Mentoring
   A. Budget preparation and negotiation
   B. Regulatory document preparation
   C. Time allocation
   D. Hospital resource utilization