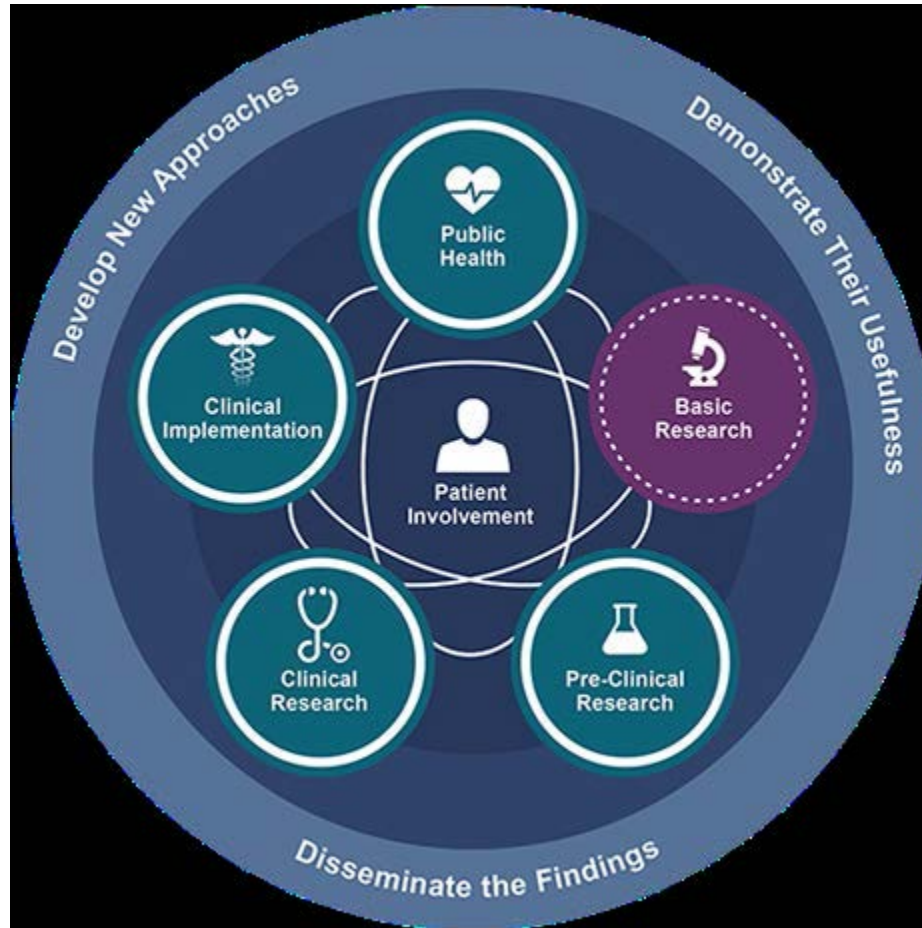


Translational Science Spectrum

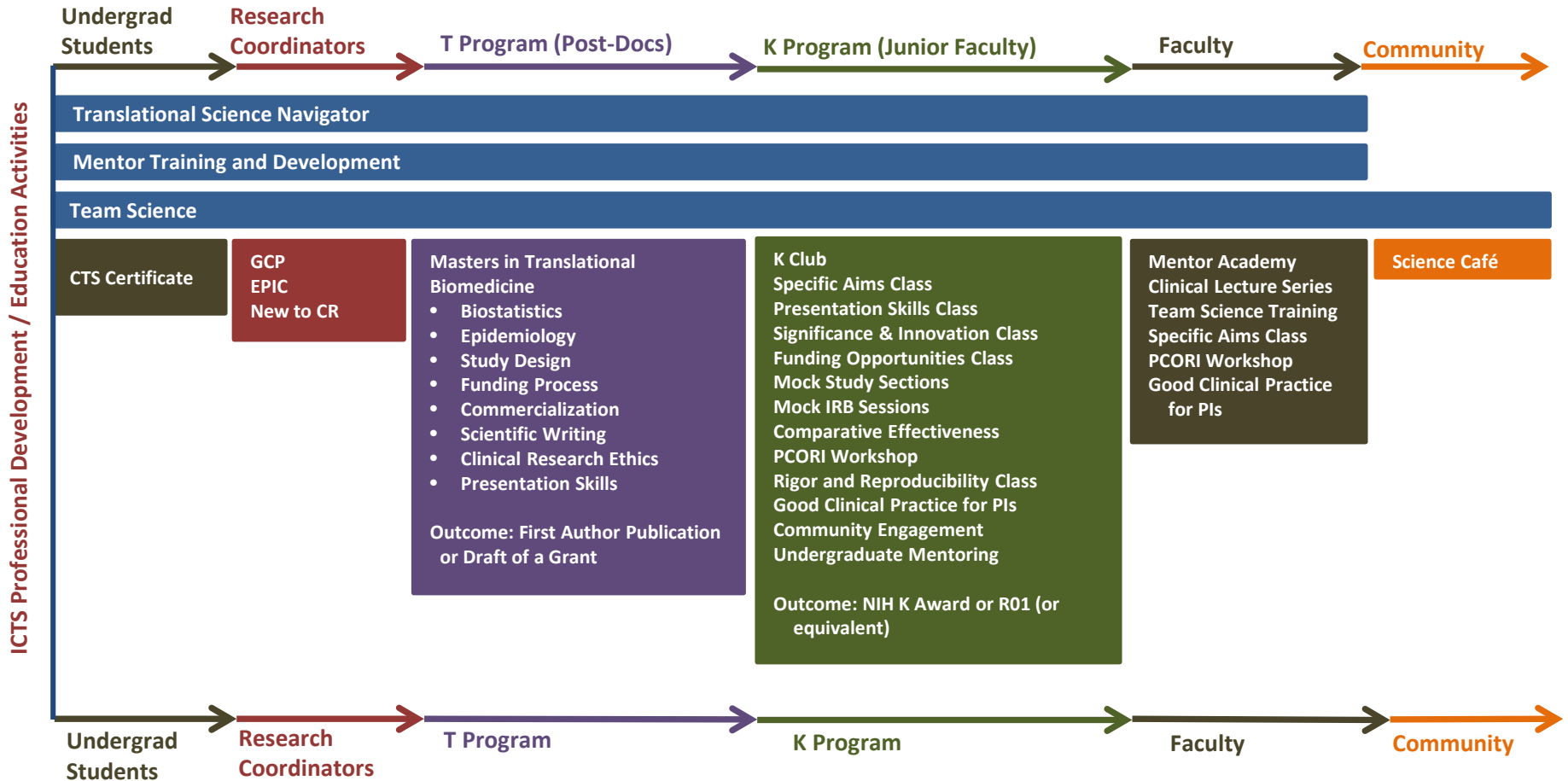


ICTS Overview



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



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

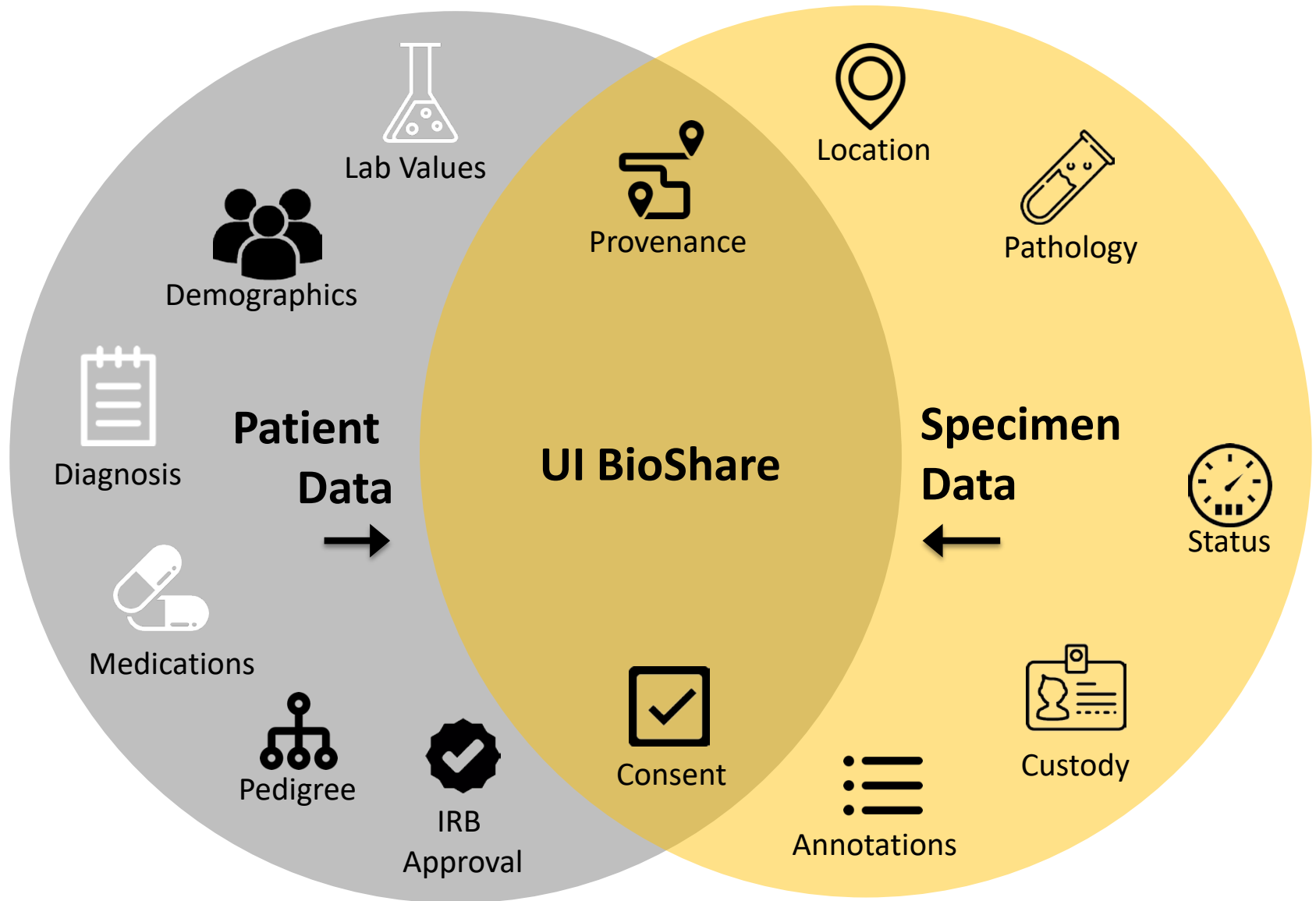


KL2 PROGRAM

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

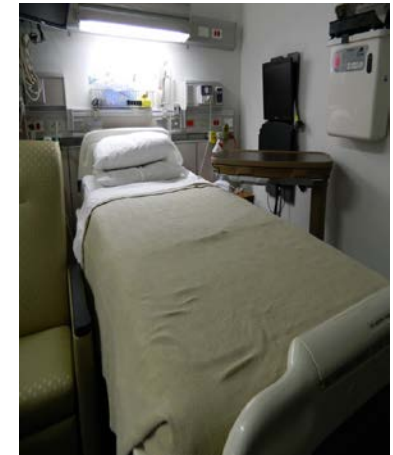
TBM NON-CREDIT CAREER DEVELOPMENT ACTIVITIES

- 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

Clinical Research Unit

- 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

Research Coordinator Core

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

Child Health Coordinator Core

- 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



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