

Clinical and Translational Science Institute



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Driven to DiscoverSM

Advancing Your Research with CTSI Expertise

An AHC Faculty Conversation with

Dr. Bruce Blazar, CTSI Director

and

Dr. David Ingbar, CTSI-Ed

Director

Helping researchers bring discoveries into practice

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Agenda



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- CTSI Director **Dr. Bruce Blazar** provides an overview of CTSI (10 minutes)
- CTSI-Ed Director **Dr. David Ingbar** provides an overview of CTSI's education and career development programs (5 minutes)
- Scholars **Alexa Pragman**, **Siobhan McMahon** and **Mark Osborn** highlight CTSI's KL2 program (10 minutes)
- **Dr. Blazar** charts CTSI's future direction (10 minutes)
- Q&A from the live and web audience (10 minutes)

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OVERVIEW OF CTSI

Dr. Bruce Blazar, CTSI Director and
CTSA Principal Investigator

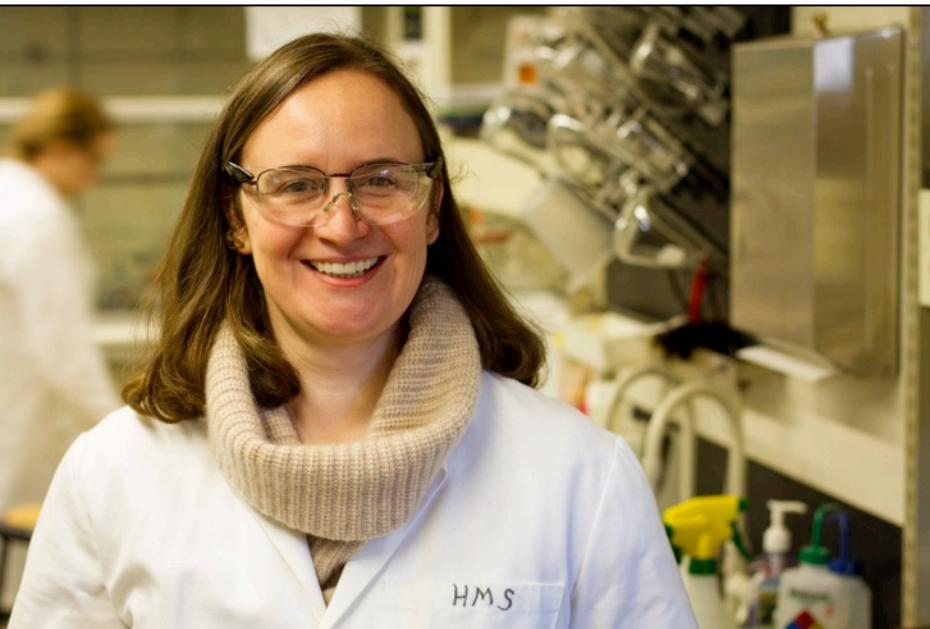
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What we do



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CTSI helps researchers be more successful in bringing discoveries into practice – to ultimately improve human health.

Here's one example:

CTSI's Office of Discovery and Translation (ODAT) is helping Dr. Valerie Pierre convert her idea into a real-world bacterial infection diagnostic tool through funding and support.

“Their expertise enhanced the quality of my translational project, and is maximizing its chance for success.”

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What we do



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CTSI helps researchers be more successful in bringing discoveries into practice – to ultimately improve human health.

Here's one example:

CTSI's Education group helped Dr. Youssef Roman launch his career and expand upon his research.

“Their career development programing went beyond scientific theories and statistics by teaching me how to convey complex scientific topics in a way that's clear and compelling.”

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Supporting your research



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- Through:
 - Consultations
 - Services, staff and space to facilitate studies
 - Education and career development
 - Tools, resources and support
 - Funding

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Specific support



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- Build out a study plan and budget
- Statistical and data management support
- Develop research protocols
- Attain regulatory and IRB approvals
- Access de-identified data
- Identify patient cohorts
- Recruit participants for studies
- Manage a study throughout its lifecycle
- Connect you with research resources and expertise

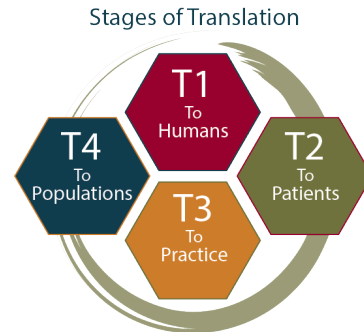
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Comprehensive support



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- CTSI supports all stages of translation
- CTSI's resources, funding and consultations are available pre- and post-award
- CTSI provides multi-site study support through MARCH, a Midwest research consortium, and PCORI-supported Greater Plains Collaborative



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Who we support



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- University of Minnesota faculty across all campuses
- Research professionals and study teams
- Community-based researchers
- Undergrad, pre-doctoral and post-doctoral students via career development programs

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Funding programs



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- Early-stage, clinical research, and later-stage award programs
- Six pilot award programs
- Current opportunities:
 - Community Health Collaborative Grants Program
 - Committee for Pharmaceutical Development
 - Community Research Van

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Investigator engagement



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231 scholars have been trained through **7** unique programs and
4,200 attendees at **312** seminars

Provided services to **650+** investigators across **12** UMN schools and
colleges and supported **465** research projects since 2012

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Investigator engagement



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Network of **160+** University and industry experts and matched **50+** research teams

Awarded more than **\$22 million** in research funds
and supported **325+** researchers

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Focus areas



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- Child health research
 - Child Health Collaborative Grant program
 - Pediatric Medical Device Translational Grant program
 - CTSA network's Child Health Research Acceleration through Multi-Site Planning grant
- Driven to Discover research at the State Fair
 - D2D Community Health Research Grant program
- Biomedical informatics
 - Clinical data repository

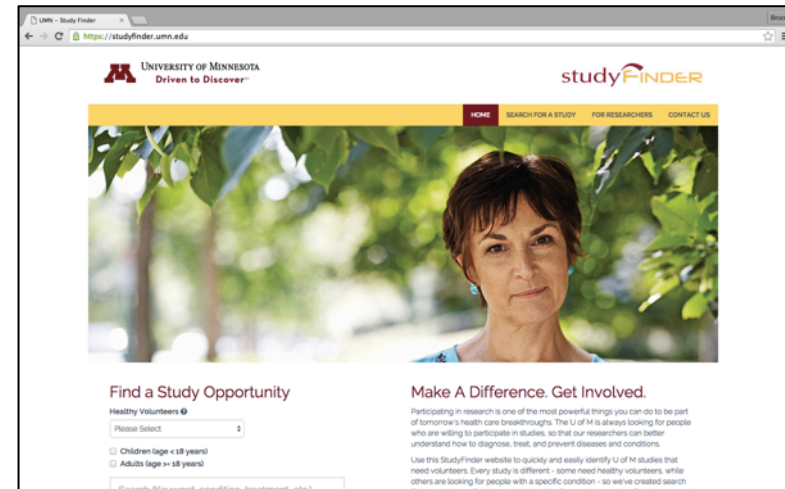
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Focus areas



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- Participant recruitment
 - Integration of clinical care and research visits
 - StudyFinder



StudyFinder.umn.edu

- Multisite study support
 - MARCH consortium
 - Greater Plain Collaborative through PCORI

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Integrating research



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Dean Brooks Jackson highlights
the Clinics and Surgery Center
and its unique mission of
integrating clinical care with
research

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Who we are



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- Five core offices located at 717 Delaware St.
 - Office of Discovery and Translation (ODAT)
 - CTSI-Ed
 - Community Engagement to Advance Research and Community Health (CEARCH)
 - Biomedical Informatics in Diehl Hall
 - Clinical Translational Research Services (CTRS)
- And the Center for Health Equity
- CTSI operates three clinical research units on campus

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CTSI'S EDUCATION AND CAREER DEVELOPMENT PROGRAMS

Dr. David Ingbar, CTSI-Ed Director

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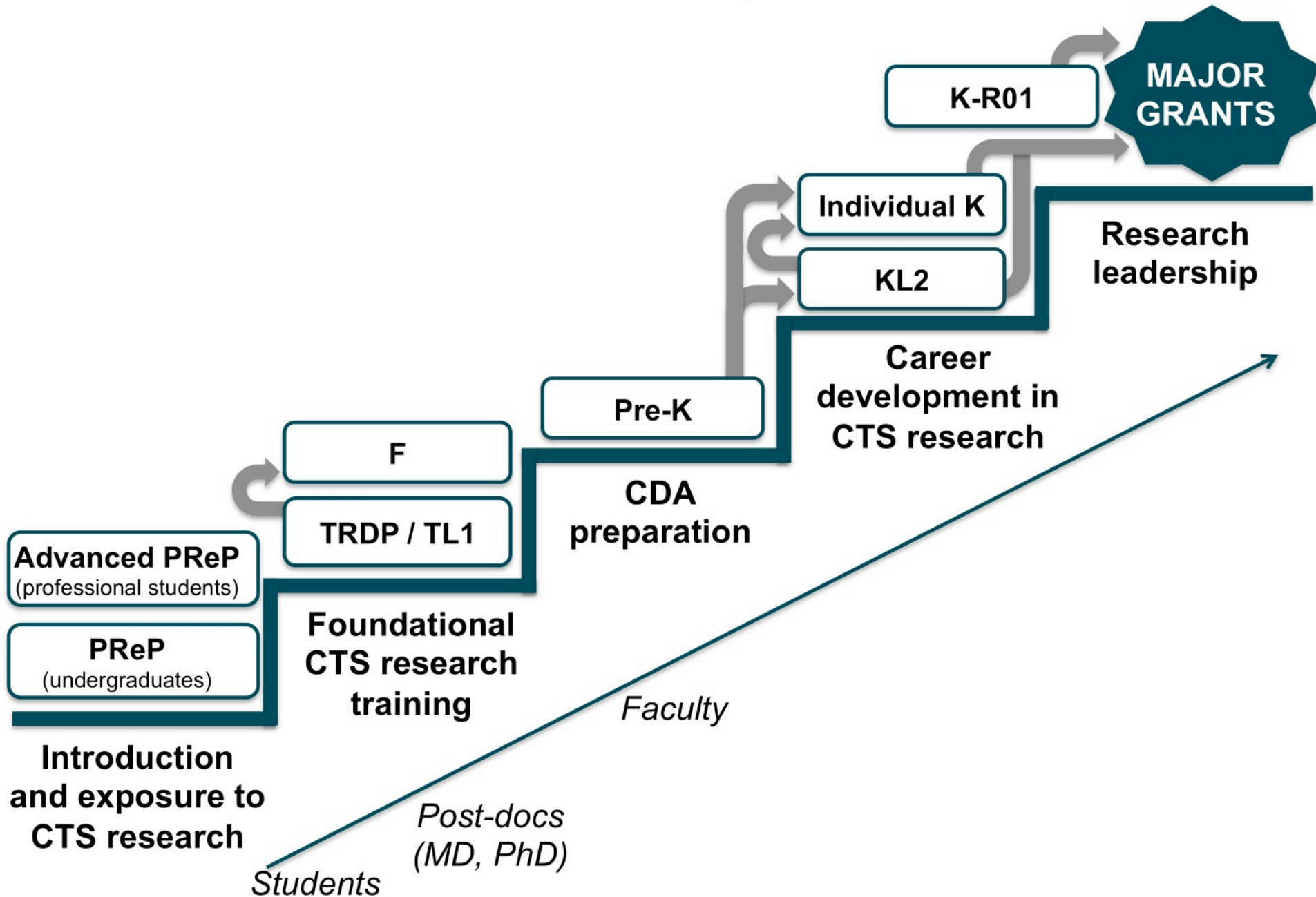
Education & Training Programs



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- Faculty Scholar Programs:
 - Pre-K Program
 - KL2 Program (Nancy Raymond)
 - K to R01 Program (Kola Okuyemi)
- Trainee Programs
 - Summer Research Programs (Kelvin Lim)
 - Undergrad Pathways to Research Program (PReP)
 - Predoctoral Advanced Research Pathways to Research Program (A-PReP) – for MD, MPH, PharmD students
 - Pre & Postdoctoral Translational Research Development Program (Yoji Shimizu)
- Mentor Training (Anne Marie Weber Main & Esam el Fakahany)
- Online Training Courses – for faculty, trainees & staff
- Career Development Seminars

CTSI-Ed Career Development Continuum



KL2 program support plan

Year	1	2	3	4	5
Designation	-----KL2-----		-----KL2'-----	-----KL2X-----	
Funding source	-----NIH CTSI-----		-----UMN AHC-----	-----Department support-----	
Time protection	-----75%-----			-----Department support-----	
Education	Required KL2 seminar, individual coursework, -----translational research <u>bootcamp</u> , +/- MS degree			Career development -----meetings,----- optional KL2 seminar	
CTSI-Ed support	----- <u>Presubmission</u> grant reviews, mock study session, grant writing assistance				
Progress reports and monitoring	6-month progress reports, mentor teams, -----and Multidisciplinary Advisory----- Committee (MAC) reviews			6-month progress reports, ----- <u>individ.</u> research & career-- advancement committees	

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Career Development Activities



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- Grant writing:
 - Annual grant writing seminar
 - Co-sponsor grant writing course (3x/year)
- Monthly career development seminars (open)
- Mentor training – Online & META
- Translational Research Bootcamp 3 day event for CTSI faculty and trainee scholars
- Online modules: GCP & others
- Developing Practice-Oriented Research Training (PORT) program (*Univ Michigan*) – for clinicians with little formal training in clinical research



Evaluation of the Lung Microbiota and Inflammation in the Progression of Chronic Obstructive Pulmonary Disease

Alexa Pragman, MD, PhD, Assistant Professor,
Medical School, Department of Medicine, Division
of Infectious Diseases
CTSI F&T and KL2 Scholar | VA Career
Development Award

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Evaluation of the Lung Microbiota and Inflammation in the Progression of COPD



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Significance

- COPD is the 3rd-leading cause of death worldwide
- The mechanisms of progression are poorly understood
- Inflammation due to a disrupted lung microbiota is a potential mechanism
 - COPD progression
 - Frequent exacerbations of COPD

KL2 project: A cross-sectional study comparing the lung microbiota of frequent and infrequent COPD exacerbators

- Oral wash and induced sputum samples to define the lung microbiota of both frequent and infrequent exacerbators
- Evaluation of systemic and lung inflammation
- Associate lung microbiota factors with inflammation

Research Question: Is the lung microbiota associated with COPD exacerbation phenotype or inflammation?

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What CTSI has meant for my career



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- Financial and social support
- Networking
- Developing skills I didn't know I needed
- External grant reviews!
- Formalizing mentorship skills and optimizing my mentoring relationships
- Offering a continuum of funding opportunities

	CAREER DEVELOPMENT AWARD Department of Veterans Affairs CLINICAL SCIENCE RESEARCH & DEVELOPMENT	NOTICE OF INTENT TO AWARD Issue Date: 08/24/2015
Application Number: 1IK2CX001095-01A2 FAIN: IK2CX001095		
Principal Investigator(s): ALEXA A PRAGMAN, MD		
Project Title: Evaluation of the Oral and Lung Microbiota and Inflammation in Chronic Obstructive Pulmonary Disease Frequent Exacerbators		
 UNIVERSITY OF MINNESOTA Notice of Grant or Contract Award Sponsored Projects Administration		
(Online Page Navigation: Main Menu > Grants > Awards > UM_NOGA Report)		

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Next steps in my career



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- 5-year independent Career Development Award at the Minneapolis VA
- Transition my research and clinical duties to the VA
- Roll my KL2 study patients into my CDA-2 study
- Continue my F&T project
- Grow my lab, look for mentoring opportunities
- Develop interventional and mechanistic studies of the lung microbiota



ENHANCING MOTIVATION FOR PHYSICAL ACTIVITY TO REDUCE THE RISK OF FALLS AMONG COMMUNITY- DWELLING OLDER ADULTS

A WELLNESS INTERVENTION

Siobhan McMahon, PhD, MPH, GNP-BC,
Assistant Professor, School of Nursing
CTSI KL2 Scholar | PCORI Site Co-PI

Interdisciplinary Mentorship Team

Alexander J Rothman, PhD,
Psychology

Jean Wyman, PhD, RN,
GNP-BC, Nursing

J Michael Oakes, PhD, Public
Health

Beth Lewis, PhD, Kinesiology

Weihua Guan, PhD, Public
Health

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Significance, objective, and approach



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Significance

- Evidence: Leg-strengthening, balance training, and walking programs reduce falls in older adults
- Limited Translation of Findings to Behavior: Physical activity levels remain low & falls are increasing
- Improve Translation: Research examining strategies that motivate older adults to engage in physical activity is scarce and inconclusive

Objective

Assess the relative influence of two unique sets of behavioral change strategies - each representing different ways of motivating people to take action: inter-personal and intra-personal when combined with an evidence-based fall-reducing physical activity protocol

Approach

Community-Based Factorial Experiment. 102 adults ≥ 70 years old randomized to 1 of 4 conditions

- 1) Physical activity only (n = 25)
- 2) Physical activity + interpersonal component (n = 25)
- 3) Physical activity + intrapersonal component (n = 25)
- 4) Physical activity + interpersonal + intrapersonal components (n = 27)

Comparable Attention

- Fitbit OnesTM
- 8 week program
 - 90 minute per week
 - Small groups (4-6)

Primary Outcome: Physical Activity

- 1) Measured directly: Accelerometers built in to Fitbit OnesTM
- 2) Self-report : CHAMPS physical activity questionnaire

- Immediately post-intervention
- 6 months post-intervention

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Impact on my career



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Leadership

Mentor

- CTSI PReP
- SoN Honor students
- UMN UROP

Lead/ Direct

KL2 research project team

Award

John A. Hartford Award (*Midwest Nursing Research Society*)*

Collaborative Team Science

Interdisciplinary Mentorship Team

PCORI/ NIA Multi-site Fall Prevention Grant (*Site Co-PI, Essentia Health*)

SoN, Adult/ Gero Coop (*Co-I*)

MN Board on Aging, Fall Prevention Project (*Consultant*)

Scholarship

Internal Grants

- Grant-In-Aid
- D2D (*State Fair Surveys*)

External Grants

- NIA/PCORI Multi-Site Fall Prevention Grant
- R01 (*pending*)
- R21 (*pending*)

Coursework /Learning

- Grant writing course
- PH courses
- Workshops

Dissemination

- Conferences
- Manuscript submission(s)

* MNRS members who have demonstrated the potential for leadership in geriatric nursing science, and who will likely improve the quality of care for older adults in the MNRS region as evidence of their scholarship

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Next steps (12 months)



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- Disseminate KL2 results
 - Conferences
 - International Society of Nutrition and Physical Activity
 - Gerontological Society of America
 - Society of Behavioral Medicine
 - National CTSA conference
 - Manuscripts focusing on
 - Primary outcome of the intervention (physical activity)
 - Psychosocial processes of physical activity behavior change among participants in this intervention
- Implement *or* revise
 - R21 ancillary for PCORI/NIA Multisite Fall Prevention Study (Co-PI)
 - R01, **Community-based intervention effects on older adults' physical activity and falls**



NEXT GENERATION CHIMERIC ANTIGEN RECEPTOR AND ENGINEERED NUCLEASE BASED TUMOR THERAPY....*and progression as a CTSI Scholar*

Mark J Osborn, PhD, Assistant Professor,
Pediatrics, Blood and Marrow Transplantation
Stem Cell Institute, Center for Genome
Engineering | KL2 Scholar

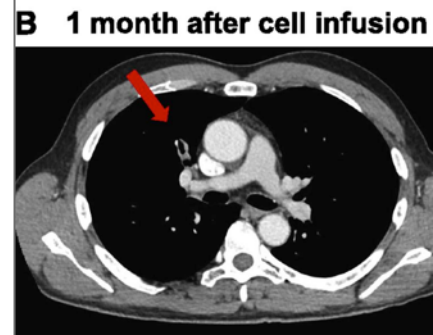
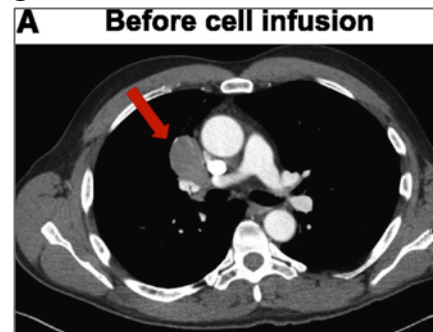
Significance



- T-cell leukemia affects adults and children with poor outcomes for relapsed disease
- Treatment is with bone marrow transplantation
 - Graft Versus Leukemia & Graft Versus Host
- Chimeric Antigen Receptor

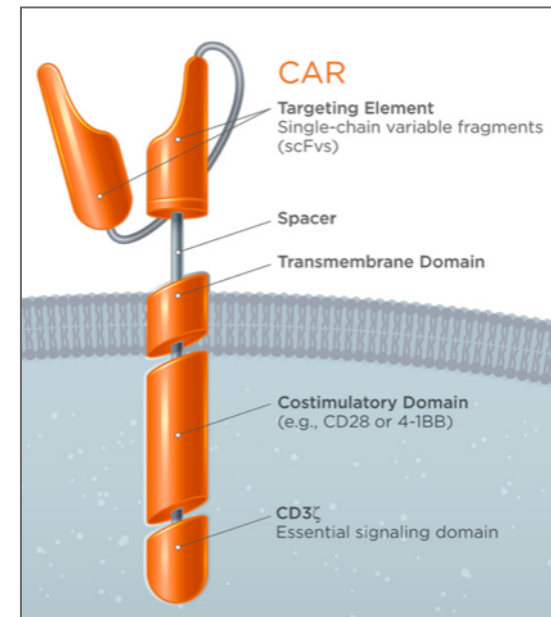
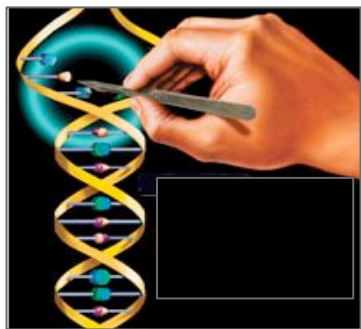
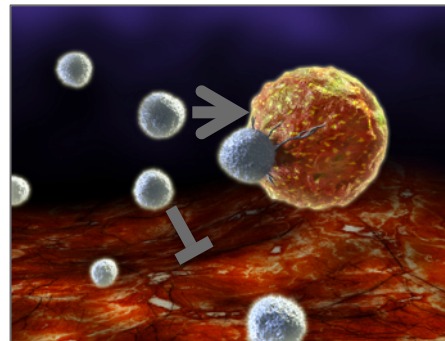
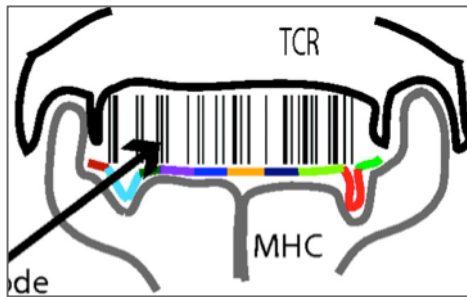
Research Question

- To Engineer an 'Off the Shelf' Pool of T-cells with Enhanced Tumor Targeting and no Host Tissue Recognition



Research Question

- Engineered T-cells: Next Generation Therapy for the Current Generation of Patients



Chimeric Antigen Receptor
Tumor Recognition

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Opportunities due to CTSI Involvement



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Research and Training

- Presentations at Local, National, and International Conferences
 - Keynote speaker: US Oncology Network
- Grant Application Submissions
- Scholarly Reports (primary research and reviews)
- Research Awards
 - Department of Pediatrics Basic Science Paper of the Year Award (2014)
 - Children's Cancer Research Fund Butterfly Award (2015)

World-Class Mentorship Team



Next Steps: Translational Application of Universal Donor T-cells for Many Malignancies

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CHARTING CTSI'S FUTURE

Dr. Bruce Blazar, CTSI Director and
CTSA Principal Investigator

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Charting our future



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- NIH grant proposal submitted in January
 - Anticipate receiving a score in late June-early July
 - Anticipate a funding decision soon after
 - Potential receipt of the award in November
- New application responded to new strategic framework from NIH's National Center for Advancing Translational Science (NCATS)

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Charting our future



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- New NCATS strategic framework calls for a re-allocation of funding for:
 - A stronger local, regional, and national CTSA network with more with more opportunities for multi-site trials, collaboration, and education
 - Deeper integration of research and clinical care
 - Improved methods and processes of research and clinical care
 - More clinical and translational education and training for all members of the “team”

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Charting our future (cont.)



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- More community engagement, including more patient advocate engagement
- Expanded informatics
- More diversity in the clinical and translational research community, especially KL2 and TL1 scholars
- Unique programmatic contributions to the national CTSA consortium

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CTSI's overarching goals



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- **Train an outstanding multidisciplinary, diverse workforce** across the spectrum of clinical and translational science research
- **Streamline methods and processes** to increase CTSI's research capacity, locally and nationally
- **Engage communities and stakeholders** to improve the process of translation and the delivery of healthcare across the lifespan
- **Contribute unique resources** to the CTSA network

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CTSI's local goals



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- Support the University's mission of an Integrated Academic Health System
 - Bio-specimen and Laboratory Services (BLS)
 - Responsibilities for research conduct at M Health
- Continue to support the OVPR's Human Research Protections Program
- Continue to build a single clinical research enterprise

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Forge stronger partnerships  UNIVERSITY OF MINNESOTA
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- To increase our local, regional and national impact
 - Hennepin County Medical Center (HCMC)
 - Minneapolis Veterans Administration Medical Center (VAMC)
 - Fairview Health Services system
 - Children's Hospital and Clinics of Minnesota
 - UMN's Duluth campus
 - Mayo Clinic's CTSA

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Helpful tools & resources



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- I2b2 cohort discovery tool – demo available today
- Clinical data repository of more than 2 million patients
- Informatics consultations to request data
- StudyFinder – stop by the kiosk today
- Research Toolkit – a one-stop resource
- Biostat walk-in appointments available 
- Community Research Van – tour earlier

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Accessing CTSI resources



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- Research Navigator



Melissa Hansen

- Invite CTSI to your departmental meeting or research day
- Sign up to receive CTSI news and information via its monthly newsletter

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CTSI

WHAT QUESTIONS DO YOU HAVE?

ONLINE AUDIENCE: SUBMIT YOUR QUESTIONS NOW