NJacts

RUTGERS
Institute for Translational
Medicine and Science

New Jersey Alliance for Clinical and Translational Science

Second Annual Retreat

An NCATS Clinical and Translational Sciences Awardee

http://njacts.rbhs.rutgers.edu

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What is a CTSA?

5 Goals:
- **Train and Cultivate Translational Science Workforce**
- **Engage Patients and Communities**
- **Integrate Special and Underserved Populations** in CTS Across the Lifespan
- **Increase the Quality and Efficiency** of CTS Research, esp. Multi-site Trials
- Advance the **Use of Cutting Edge Informatics**

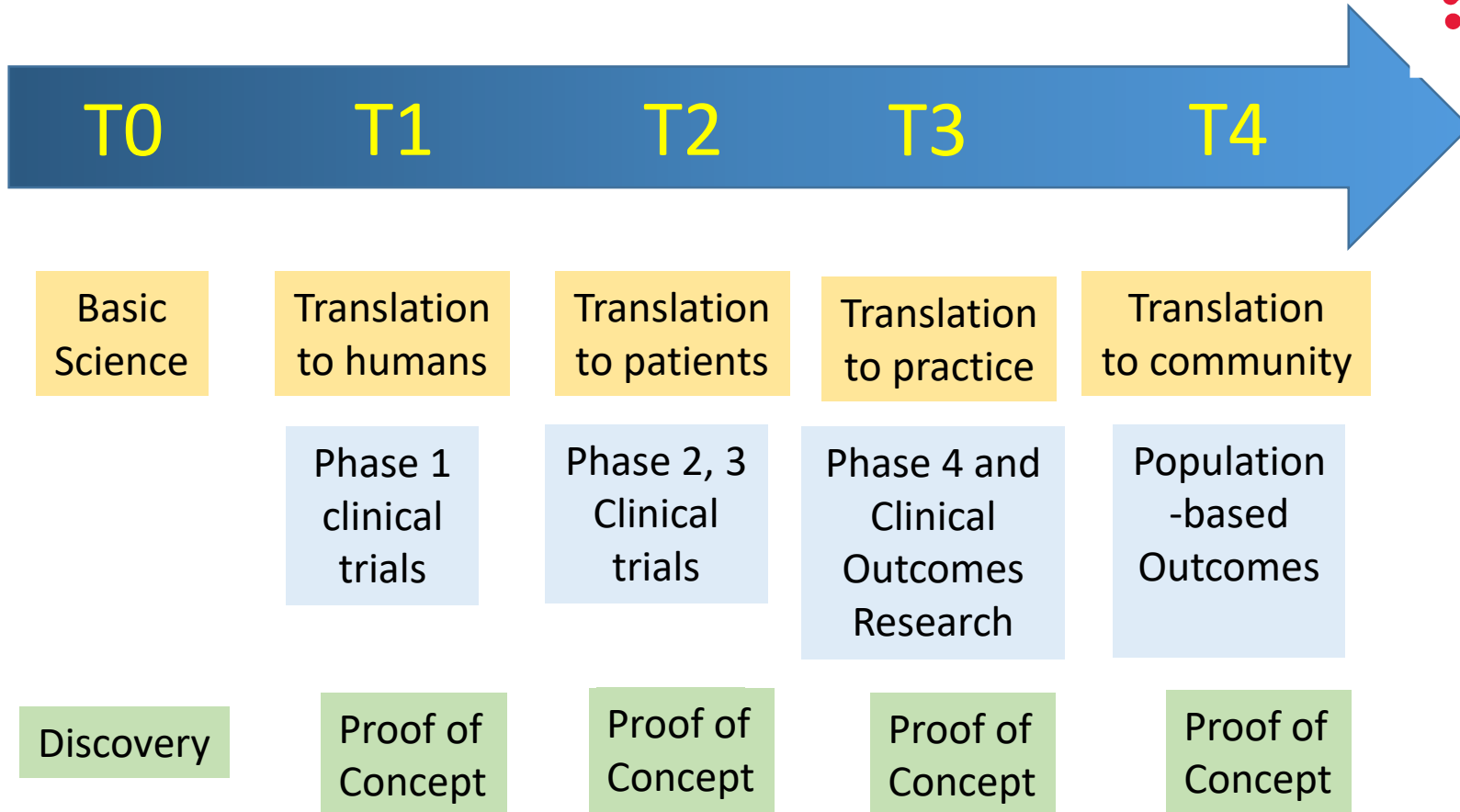| Basic Research	Translation To Humans	Translation To Patients	Translation To Practice	Translation To Community

NIH's Largest Infrastructure and Training Award

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Translational Science Is a Continuum

NJacts

T0	T1	T2	T3	T4
Basic Science	Translation to humans	Translation to patients	Translation to practice	Translation to community
	Phase 1 clinical trials	Phase 2, 3 Clinical trials	Phase 4 and Clinical Outcomes Research	Population-based Outcomes
Discovery	Proof of Concept	Proof of Concept	Proof of Concept	Proof of Concept

Academic assets for commercialization include: new drugs, devices, diagnostics and software

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BIOMEDICAL AND HEALTH SCIENCES

What/Who is NJ ACTS?

NJ ACTS is:

- Alliance of NJ academic institutions with partners from industry, clinical, state, and community
- Based in the Rutgers Institute for Translational Medicine and Science (RITMS)
- NIH Components:
  - Hub award of 14 Cores (UL1)
  - Institutional Career Development Award (KL2)
  - Institutional Training Award (TL1)
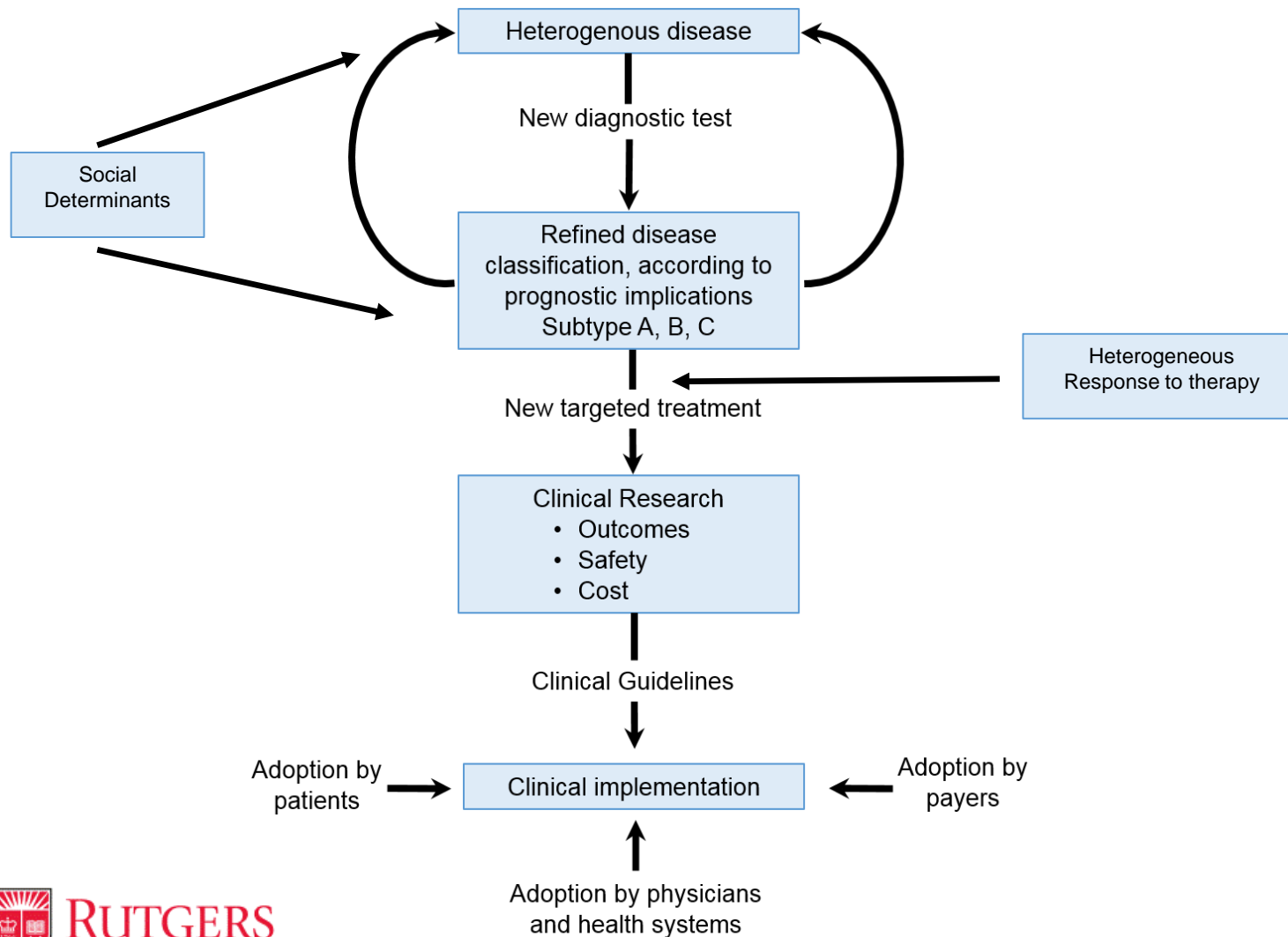
$29 Million from NIH – Total of $45 Million Investment

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NJACTS Core Leads and Co-leads

Heterogeneity in Disease and Response to Therapy

Modified after Jamison JL et al NEJM 2015

Successes

First External Advisory Board Review:

"There was consensus that NJ ACTS made immense and impressive strides."

"There has been amazing level of productivity."

"The level of achievement by this time is outstanding and the ultimate potential fro NJ ACTS to be one of the exemplar CTSAs in the US."

Challenges

First External Advisory Board Review:

"The EAB encouraged not to re-invent the wheel, leverage best CTSA practices."

"Remember a CTSA Hub is a research services and education institute."

"The Hub needs to leverage communitarian scientists as leaders, those committed to serve everyone else."

Year 2 Retreat

Service

Innovation

Career Development

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National Center for Advancing Translational Sciences

Cohort Building

- **Health Care Worker Cohort: (NCATS supplement)**
  - **Prospective longitudinal study with over 5200 participants studying natural history of COVID-19 infectivity, amassing 27,200 biospecimens.**
- **Establishing a community-based approach for COVID-19 testing in vulnerable populations (n=2000) (RADx)**
- **Mother-child dyad cohort in predicting allergic diseases (NJ ACTS, UIC and UNC) (n=700); Duke TINS; CD2H (Supplement, submitted)**
- **ACTV1 and ACTV2 sites activated**

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NIH
National Center for Advancing Translational Sciences

Mission of the RBHS Clinical Trials Office

- Improve **efficiency** of start-up processes

- Improve the quality of clinical trials conducted at RBHS & assure that studies consistently meet **recruitment** targets

- Assure compliance with applicable regulations (specifically with regard to **clinical research billing**)

- **Standardize** clinical research policies and procedures across RBHS

NJ ACTS Legacy

- **KL2 Awardees (Eight)**

- **TL1 Awardees (Thirteen)**

- **Pilot Grant Awardees (Twenty-seven)**
  - Supplemented by NJ Foundation now support totals $600,000/year

CTSA Supplements
Awarded Supplements

AWARD NAME	STATUS	AWARD AMOUNT	PI(s)
RADx UP	Awarded	$19,360,000	Hudson (contact), Barrett, Blaser, Hill, Jimenez
COVID Supplement	Awarded	$1,482,000	Panettieri (Contact), Blaser, Coromilas, Fiedler, Carson, Rawal, Horton, Roy
iCorp Supplement with University of Alabama	Awarded	$65,520	Jeff Robinson and Dunbar Birnie
Combat COVID Supplement with NYU (TRICON)	Awarded	$100,000	Soko, Barr, Sonnenberg

Pending Supplements

AWARD NAME	STATUS	AWARD AMOUNT	PI(s)
Quality Assuarance/Quality Control Supplement	Pending	$850,773	Admin Supplement
Diversity Supplement (2)	Pending	$300,000	Peck, Akhabeu
U01 Supplement with UNC and UIC	Pending	$1,044,258	Panettieri, Blaser, Einstein
R21 Supplement with University of Penn	Pending	$137,500	Zhi Wei (NJIT)
Informatics Supplement with Pitt, Harvard, and Boston VA	Pending	$133,333	Foran

32 NJACTS Publications

An updated list of NJACTS publications can be found at https://njacts.rbhs.rutgers.edu/about/cite-the-ctsa/

1. Asthma and COVID: What Are the Important Questions?

2. Dexamethasone rescues TGF-beta 1-mediated beta(2)-adrenergic receptor dysfunction and attenuates phosphodiesterase 4D expression in human airway smooth muscle cells

3. A practical introduction to Bayesian estimation of causal effects: Parametric and nonparametric approaches.

4. Free Fatty Acid Receptor 1/4 (FFAR1/4) Agonists, GW9508 and TAK875, Attenuate Cell Shortening as Broncho-Protectors in Human Airway Smooth Muscle (HASM) Cells

5. Blocking YKL-40 (Chitinase-Like Protein Chitinase 3) Reverses IL-13/IL-4-Induced Hyporesponsiveness to Bronchodilators in Human Small Airways and in Human Airway Smooth Muscle Cells

6. Rhinovirus (RV) C15 Decreases β2 Adrenergic Receptor (β2AR) Agonist-Induced Bronchodilation and Camp Levels in Human Small Airways and Airway Smooth Muscle (HASM)

7. Cholecystokinin Evokes Excitation-Contraction Coupling in Human Airway Smooth Muscle Cells

8. Dermal Sensitizer 1-Chloro-2,4-Dinitrobenzene (DNCB) Induces TSLP Expression in Precision-Cut Human Lung Slices

9. Low oxygen tension differentially regulates the expression of placental solute carriers and ABC transporters

10. Possible Unintended Consequences for Pregnant Women of Legalizing Cannabis Use

11. Intergenerational Effects of Welfare Reform: Adolescent Delinquent and Risky Behaviors

12. Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Is Comparable in Clinical Samples Preserved in Saline or Viral Transport Medium

13. Benzodiazepine Treatment and Fracture Risk in Young Persons With Anxiety Disorders

14. Social and medical risk factors associated with supportive needs in the first year following localized prostate cancer treatment

15. Genetic analysis of the cooperative tumorigenic effects of targeted deletions of tumor suppressors Rb1, Trp53, Men1, and Pten in neuroendocrine tumors in mice

16. Beyond Black and White: Mapping Misclassification of Medicare Beneficiaries Race and Ethnicity

17. Comparison of Machine Learning and Land Use Regression for fine scale spatiotemporal estimation of ambient air pollution: Modeling ozone concentrations across the contiguous United States

18. SCHEEPDOG: Programming Electric Cues to Dynamically Herd Large-Scale Cell Migration

19. Application of Healthcare 'Big Data' in CNS Drug Research: The Example of the Neurological and Mental Health Global Epidemiology Network (NeuroGEN)

20. Effectiveness of mandatory peer review to reduce antipsychotic prescriptions for Medicaid-insured children

21. Effectiveness of Mandatory Peer Review to Reduce Antipsychotic Prescriptions for Medicaid-insured Children

22. National Partnership to Improve Dementia Care in Nursing Homes Campaign: State and Facility Strategies, Impact, and Antipsychotic Reduction Outcomes

23. Disinformation, Misinformation and Inequality-Driven Mistrust in the Time of COVID-19: Lessons Unlearned from AIDS Denialism

24. CD2 Regulates Pathogenesis of Asthma Induced by House Dust Mice Extract

25. Collagen and Elastin Disarray Mechanisms Mediating Aortic Stiffness in Aging Pre-Menopausal Female Monkeys

26. School and Community Involvement of Adolescents with Chronic Health Conditions

27. Ad Blocking Whitelist Prediction for Online Publishers

28. Possible unintended consequences for pregnant women of legalizing cannabis use

29. Budesonide enhances agonist-induced bronchodilation in human small airways by increasing cAMP production in airway smooth muscle.

30. Acute Care, Prescription Opioid Use, and Overdose Following Discontinuation of Long-Term Buprenorphine Treatment for Opioid Use Disorder

31. Thread Structure Learning on Online Health Forums With Partially Labeled Data

32. Rhinovirus C15 Induces Airway Hyperresponsiveness via Calcium Mobilization in Airway Smooth Muscle

What Does NJ ACTS Mean to Me?

- Pilot grant funding
- Availability of new tools for research
- Access to new participant populations through Community and Special Populations
- Training for students, staff, faculty in CTS and new tools
- For junior faculty, career development awards
- Student and postdoc training grants slots
- Improved efficiency through hospital systems
- FOA's from NCATS exclusively for CTSA members

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NIH National Center for Advancing Translational Sciences

NJACTS Core Leads and Co-leads
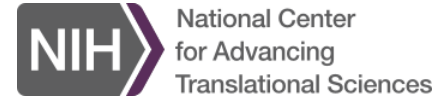
2020 NJ ACTS Retreat
Informatics Core - Service
November 13, 2020

9:00 am - 3:00 pm

New Jersey Alliance for Clinical and Translational Science

Informatics Core Leads and Co-leads

Frank Sonnenberg, MD
Professor of Medicine, RWJMS
CMIO RWJBH-Rutgers Health Medical Group

David J. Foran, PhD
Professor of Pathology, RWJMS
CIO & Exec. Dir., Comp. Imaging & Biomedical Informatics
Rutgers Cancer Institute of New Jersey

Barr von Oehsen, PhD
Associate Vice president
Rutgers Office of Advanced Research Computing

Stephen Crystal, PhD
Distinguished Research Professor
Director, Center for Health Services Research
Rutgers Institute for Health (IFH)

Yi Chen, PhD
Leir Chair & Professor of Business Data Science
New Jersey Institute of Technology

New Jersey Alliance for Clinical and Translational Science

Informatics Core Original Aims

- Integrate data from disparate clinical and research sources and expand an existing IRB-, HIPAA- and Federal Information Security Management Act (FISMA) -compliant clinical research data warehouse (CRDW) in a protected environment that makes linked data accessible to researchers.

- Enhance informatics for clinical and translational research to foster the rapid deployment of research findings into clinical practice. These capabilities include clinical trial management, data capture and dynamic clinical decision support delivered via electronic health records.

- Augment analytics capabilities across the research enterprise including acquisition, licensing, linkage and maintenance of large administrative data sets on secure accessible platforms, advanced analytics methods, and support for systems and computational biology.

- Link the science of informatics to training across the workforce continuum.

New Jersey Alliance for Clinical and Translational Science

Epic together.

Timeline

Today

April 30, 2021

October 1, 2021

GO LIVE 2
10/1/21
BHMG Practices
RWJ - Somerset

April 2, 2022

GO LIVE 3
4/2/22
RWJ – New Brunswick,
Hamilton, Rahway,
Bristol-Myers Squibb,
CINJ Infusion Center

GO LIVE 4
Monmouth, Unterberg
Children's, Monmouth South,
Community, Behavioral Health
at Toms River, UBHC

GO LIVE 6
Jersey City, Newark Beth
Israel, Children's of NJ

Ambulatory and Acute Build/Adopt,
Test, Train, & Site Readiness
Assessment

GO LIVE 1
4/30/21
RWJ-PE, RWJMS,
CINJ Physician Practice
Eric B. Chandler

GO LIVE 5
St. Barnabas, Clara Maass

GO LIVE 7
CSH
(Timing subject to change)

2020	2021	2022	2023

2nd Qtr.	3rd Qtr.	4th Qtr.	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.

Acquired Practice Implementation Team

Integration of CINJ-CRDW w/ EPIC

- Rutgers/RWJBH Data Governance Council (DGC) has been established

- First Rutgers/RWJBH formal data use agreement has been approved.
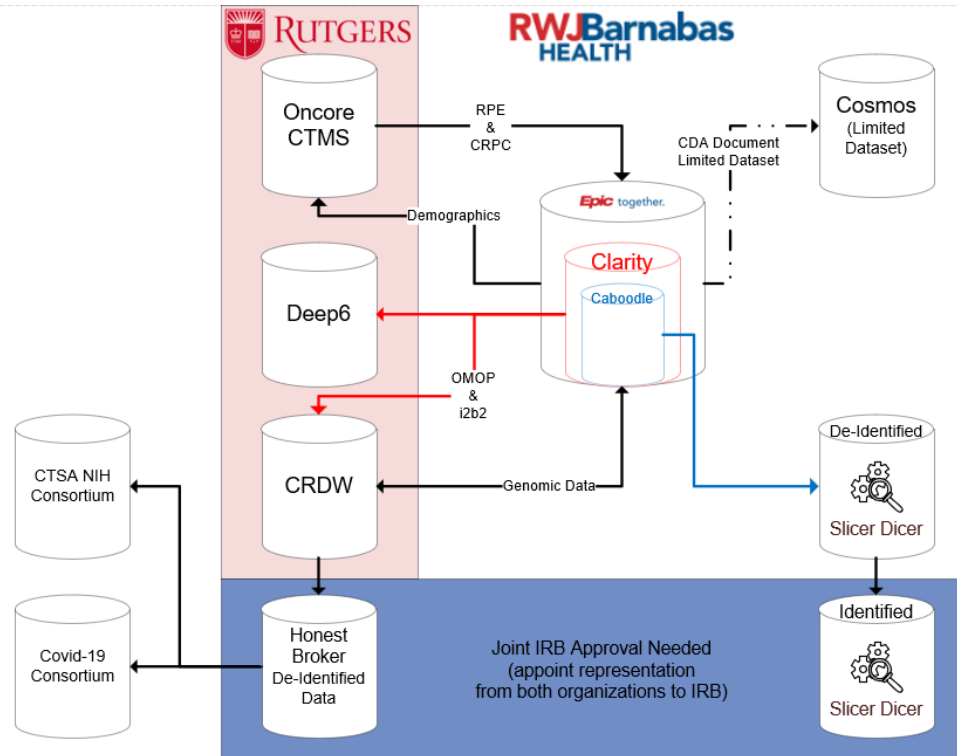
Rutgers Office of Advanced Research Computing (OARC) Connections

- Genomics apps
- SAS
- SPSS
- STATA
- R
- R-Studio
- TensorFlow
- Caffe
- PyTorch
- …any open-source app
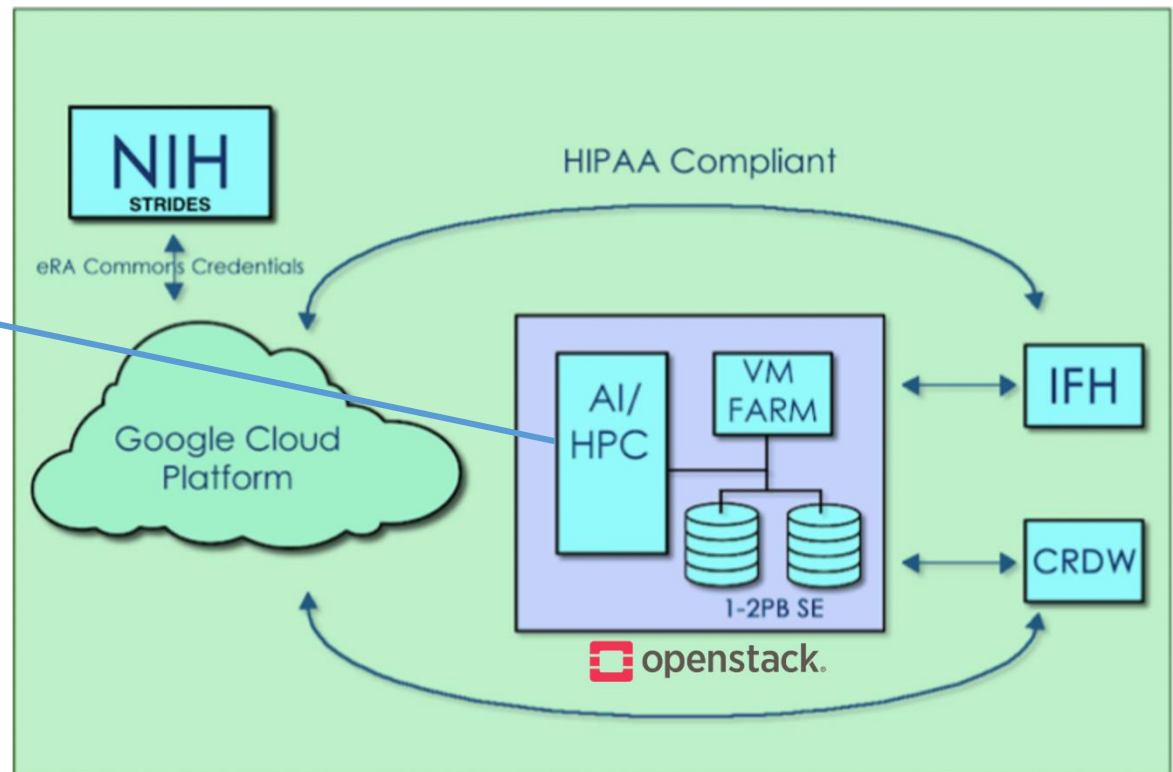
COVID 19 RWJBH- Rutgers Collaboration and Multi-Center Consortiums
(funded by CTSA supplement, supplement PI: Soko Setoguchi)

Protected RWJBH Platform

PI: Joe Jaeger

RWJBH EHRs

RWJBH COVID Data Tables

Secure FTP

Protected Rutgers CRDW

RWJBH COVID Data Tables

RWJBH COVID Data in OMOP (limited dataset)

Central COMBATCOVID Database (OMOP)

Data Analysis for COVID Research Studies

PI: Soko Setoguchi
CoI: David Foran, Barr Oehsen
Frank Sonnenberg, Rey Panettieri

Secure FTP

Access to N3C platform To Analyze data

Protected Platform for N3C (NIH NCATS)

Central N3C Database on Enclave (OMOP)

Protected Platform for COMBATCOVID (NYU Langone)

Central COMBATCOVID Database (OMOP)

PI: Stephen Johnson

RWJBH: Robert Wood Johnson Barnabas Health, EHR: Electronic health record, NJ ACTS: New Jersey Alliance for Clinical and Translational Science, N3C: National COVID COHORT COLLABORATIVE, NCATS: National Center for Advancing Translational Science, NYU: New York University, COMBATCOVID: Consortium for Multisite Biomedical Analytics and Trials on COVID-19

Informatics Core Progress to Date 3

Rutgers Institute for Health work with large administrative data sets including analyses of opioid use and related outcomes

Selection and beginning of implementation of Epic as enterprise-wide EMR for Rutgers and RWJBH

Selection and implementation of OnCore as enterprise CTMS

Deep6 AI Phase 1 pilot completed to identify cohorts for clinical research

Machine learning collaboration with Princeton University in behavioral health

NJIT collaboration on Natural Language Processing for extraction of data from EHRs

NJIT Informatics Projects

- Analyzing and Supporting Online Health Communities
  - Chen developed a novel recommendation system to help patients find relevant information and keep engaged (ACM CIKM 2020)
  - Chen developed a machine learning model that differentiates descriptions of experience versus hearsays in user-generated content, contributing to trust-worthy knowledge discovery (ACM CIKM 2020)
  - Chen developed machine learning techniques for analyzing discussion forum structures to improve information processing quality (IEEE TCSS 2019)

- Claims data analytics: Chen developed a machine learning model that makes personalized risk prediction of adverse drug events based on claims data, toward safer treatments for patients (IEEE BigData 2020)

- Information extraction on clinic data: Foran and Chen are developing techniques for biomarker extraction from pathology reports, toward more comprehensive and accurate clinic data warehouse.

Core Interactions
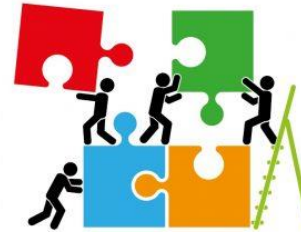
Core	Interaction
Community	Gathering requirements to identify data elements specific to community medicine to be incorporated with existing CRDW data dictionary and expansion of ETL
BERD	Establishing the workflows and analytic pipelines to allow the growing corpus of data within the CRDW to undergo systematic quantitative analysis
Regulatory	Worked together to establish and refine the mission and functionality of the new, single overarching Data Governance Council to coordinate efforts across the academic and health care systems. Established first Data Use Agreement between Rutgers and RWJBH
Special Populations	Modified data model and ETL for CRDW to accommodate incorporation of COVID data to identify disparities in healthcare delivery
Pilots	Collaborative NLP project with NJIT (Yi)
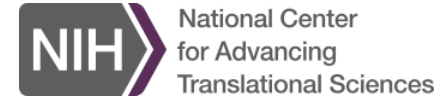
Community Engagement Core
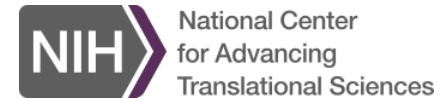
Shawna Hudson, PhD
Alfred Tallia, MD, MPH

November 13, 2020

New Jersey Alliance for Clinical and Translational Science

SERVICE

- COVID-directed and other activities
- Establishing new collaborations and providing access to instruments/tools for translational research
- Innovative approaches to address community needs
- Advancing the careers of our entire workforce
- Measuring success
- Future plans to provide services to the NJ ACTS community

New Jersey Alliance for Clinical and Translational Science

COVID-19 DIRECTED ACTIVITIES
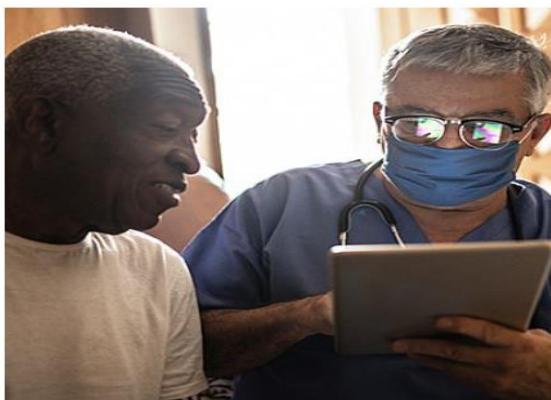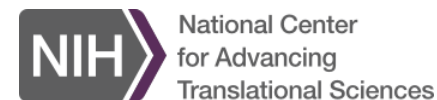
Rutgers Awarded $5 Million Grant from NIH to Improve Access to COVID-19 Testing within Underserved and Vulnerable Communities

NJ HEROES TOO

The New **J**ersey **H**ealthcare **E**ssential Wo**R**ker **O**utreach and **E**ducation **S**tudy - **T**esting **O**verlooked **O**ccupations, co-designed with community and healthcare organization partners through Virtual Community Conversations, aims to better understand COVID-19 testing patterns among underserved and vulnerable populations; strengthen the data on disparities in infection rates, disease progression and outcomes; and develop strategies to reduce the disparities in COVID-19 testing. This predominantly virtual program focuses on increasing testing in the Black and Latinx communities disproportionately affected by COVID-19 in Passaic, Union, Essex, and Middlesex counties.

New Jersey Alliance for Clinical and Translational Science

NEW COLLABORATIONS
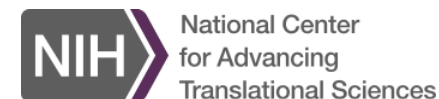
Shawna Hudson, Ph.D. (Contact Principal Investigator)
Professor and Research Division Chief,
Department of Family Medicine & Community Health
Director, Center Advancing Research and Evaluation
for Patient-Centered Care (CARE-PC)
Rutgers Robert Wood Johnson Medical School
Co-Director of Community Engagement, NJ Alliance for
Clinical and Translational Science (NJ ACTS)
EMAIL: hudsonsh@rutgers.edu

Martin Blaser, M.D.
Henry Rutgers Chair of the Human Microbiome
Professor of Medicine and Microbiology – RWJMS
Director, Center for Advanced Biotechnology & Medicine
Rutgers University
EMAIL: martin.blaser@cabm.rutgers.edu

Emily Barrett, Ph.D.
Associate Professor
Department of Biostatistics and Epidemiology
Rutgers School of Public Health Environmental &
Occupational Health Sciences Institute
EMAIL: emily.barrett@eohsi.rutgers.edu

Diane Hill, Ph.D.
Assistant Chancellor, University-Community Partnerships
Office of the Chancellor
Assistant Professor of Professional Practice
School of Public Affairs and Administration
Rutgers University-Newark
EMAIL: dianeh@newark.rutgers.edu

Manny Jimenez, M.D., M.S., F.A.A.P.
Assistant Professor of Pediatrics & Family Medicine
and Community Health
Director, Developmental & Behavioral Pediatrics Education
Boggs Center on Developmental Disabilities
Rutgers Robert Wood Johnson Medical School
EMAIL: jimenema@rwjms.rutgers.edu

Reynold Panettieri, Jr., M.D.
Professor of Medicine, Robert Wood Johnson Medical School
Vice Chancellor, Clinical & Translational Science
Director, Rutgers Institute for Translational Medicine & Science
Director, NJ Alliance for Clinical & Translational Science (NJ ACTS)
Emeritus Professor of Medicine, University of Pennsylvania
Child Health Institute of New Jersey
Rutgers, The State University of New Jersey
EMAIL: rp856@rbhs.rutgers.edu
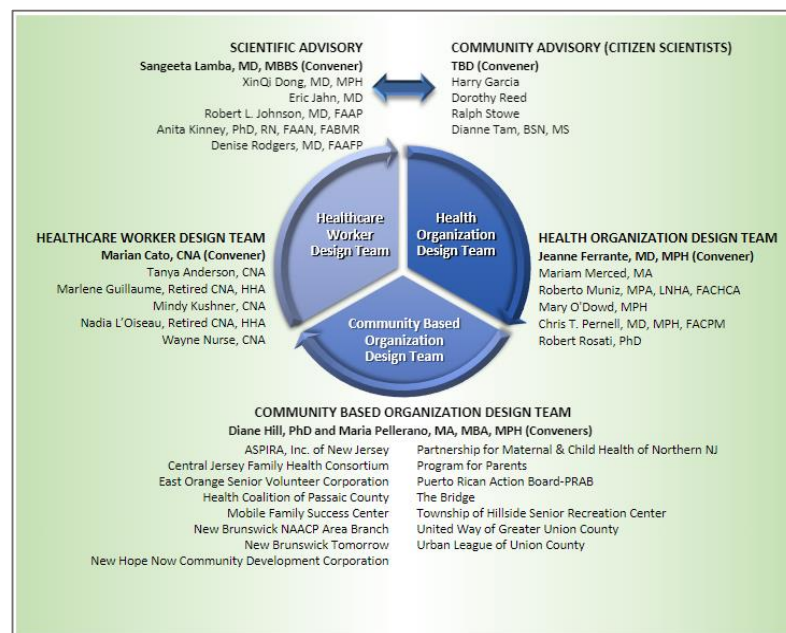
New Jersey Alliance for Clinical and Translational Science
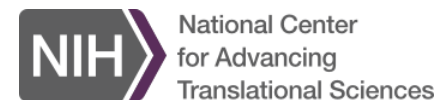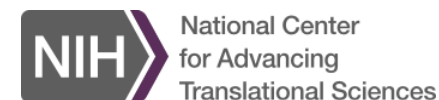
NEW COLLABORATIONS

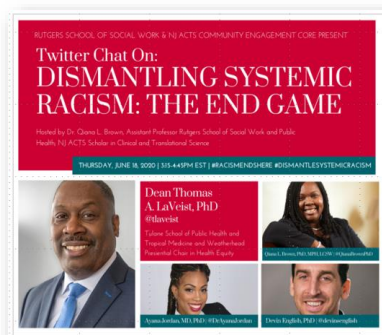New Jersey Alliance for Clinical and Translational Science

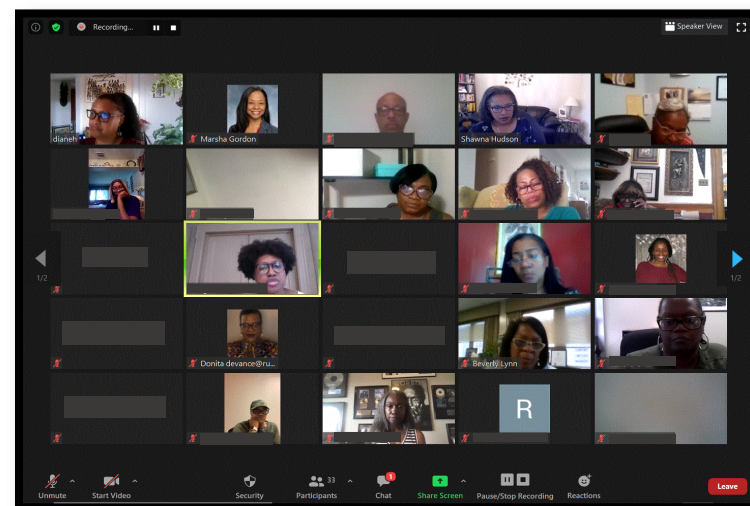# INNOVATIVE APPROACHES TO ADDRESS COMMUNITY NEEDS

Twitter Chat: Dismantling Systemic Racism: The End Game

June 18th, 2020

- Generated over 2.3 million impressions

- 564 participants

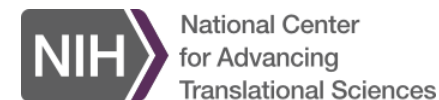- A total of 1132 tweets in 5 days (780 of which occurred on the day of the event)

Community Engagement Virtual Salons & Virtual Community Conversations

New Jersey Alliance for Clinical and Translational Science

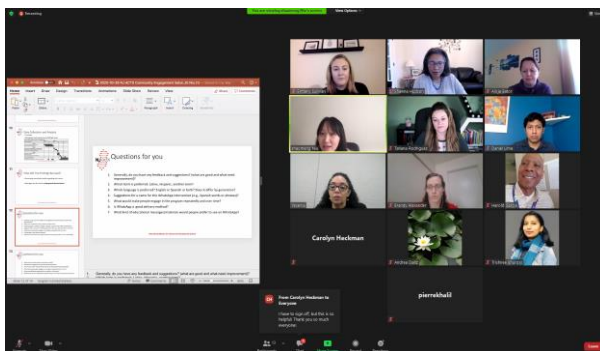# ADVANCING CAREERS OF THE ENTIRE WORKFORCE

PRESENTATION

Academic Careers in the Era of Team Science
January 28, 2020
The Cancer Institute of New Jersey

From left to right: Samuel S. Wang, Shawna Hudson, and Edmund Lattime.

Community Engagement Virtual Salons

Partnership and Innovation Accelerator and Advancing Health Equity and Social Justice Pilot Grants

2019 PIAP Recipients

Kathryn Edin, PhD   Pamela Rothpletz-Puglia, PhD   Joachim Sackey, PhD   Usha Ramachandran, PhD   Helmut Zarbl, PhD

2020 PIAP and AHESJ Grant Recipients

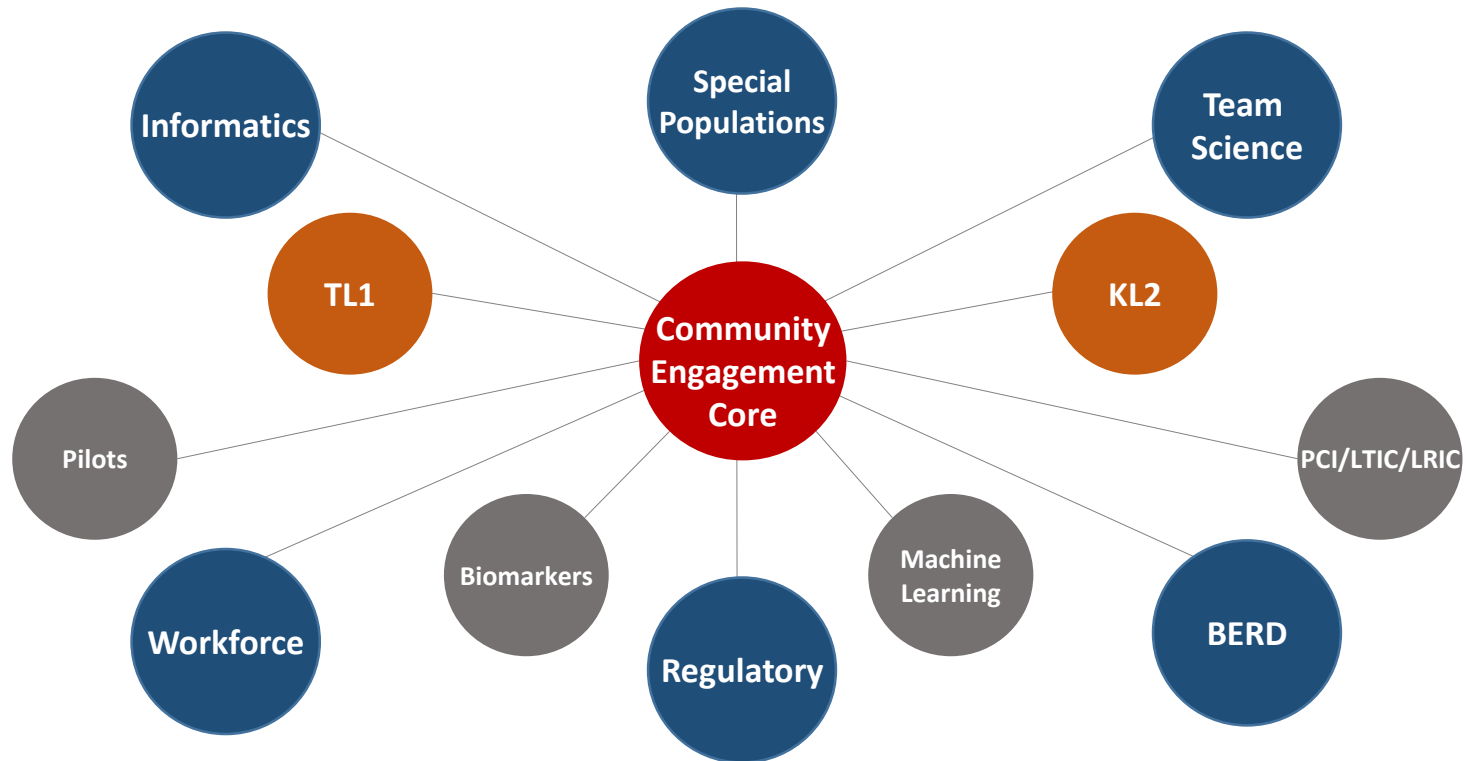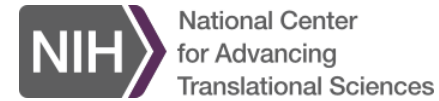Slawa Rokicki, PhD, MS   Walter Zahorodny, PhD   Jose Centeno, PhD   Christine Dimaculangan, PharmD   Richard Marlink, MD

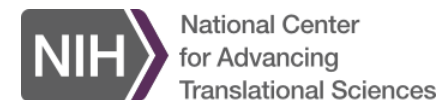**New Jersey Alliance for Clinical and Translational Science**

# CORE INTERACTIONS: COLLABORATIONS AND ACTIVITIES

New Jersey Alliance for Clinical and Translational Science

MEASURING 2020 SUCCESS

- Forged partnerships with 16 new community based organizations and 2 healthcare organizations
- 10 consultations with internal and external collaborators and lay community members and 5 referrals to Rutgers resources.
- 25 total PIAP and AHESJ applications received
    - 2 PIAP proposals awarded
    - 3 AHESJ proposals awarded
- Submitted 2 applications for funding (PCORI and RADxUP)
- Received NIH RADxUP funding for $5 million over 2 years
- Papers and presentations
    - Soon Ae Chun, Alen Chih-Yuan Li, Amir Toliyat, and **James Geller**. 2020. **Tracking Citizen's Concerns during COVID-19 Pandemic.** In The 21st Annual International Conference on Digital Government Research.

    - Liu H, Perl Y, **Geller J**. **Concept placement using BERT trained by transforming and summarizing biomedical ontology structure**. J Biomed Inform. 2020 Oct 22;112:103607.

    - **Mackie TI**, Ramella L, Schaefer AJ, Sridhar M, Carter AS, Eisenhower A, Ibitamuno GT, Petruccelli M, Hudson SV, Sheldrick RC. **Multi-method process maps: An interdisciplinary approach to investigate ad hoc modifications in protocol-driven interventions**. J Clin Transl Sci. 2020 Feb 26;4(3):260-269.

    - **Hudson SV, Tallia A, Gordon M, Sullivan B, Bator A, Macenat M, Daitz A. Community Engagement in a Virtual World: Tweets Salons and Conversations.** In the 2020 Fall CTSA Program Meeting.
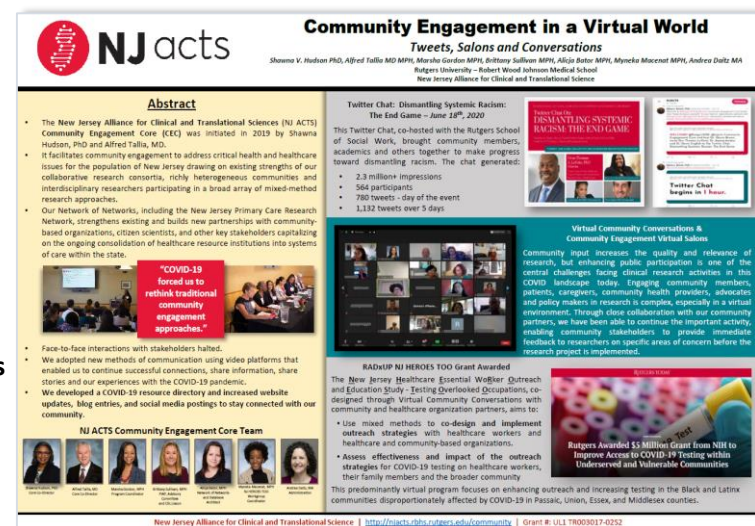
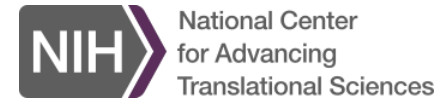**New Jersey Alliance for Clinical and Translational Science**

FUTURE PLANS TO PROVIDE SERVICES TO NJ ACTS COMMUNITY
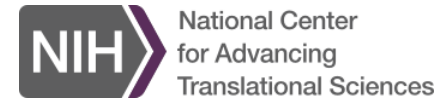
- **Expand the Network of Networks** which has grown from 250 connections in 2019 to 600+ connections in 2020.
  - Community based organizations.
  - Healthcare organizations.
  - Local, state, and national government organizations.
  - Non-profit organizations.

- **Offer Citizen Science Training** to grow our cohort of research savvy community members and health care stakeholders able to offer valuable insight, suggestions and feedback for translational science projects.
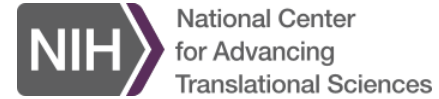
New Jersey Alliance for Clinical and Translational Science

QUESTIONS?

New Jersey Alliance for Clinical and Translational Science

Biostatistics, Epidemiology, and Research Design (BERD)

New Jersey Alliance for Clinical and Translational Science

BERD Leads and Co-leads
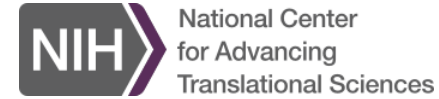
BERD Co-Director

Perry Halkitis, PhD, MS, MPH

Dean of Rutgers SPH

Professor of Urban-Global Public Health

Professor of Biostatistics

BERD Co-Director

Jason Roy, PhD

Chair of Biostatistics & Epidemiology

Professor of Biostatistics

New Jersey Alliance for Clinical and Translational Science

BERD Team
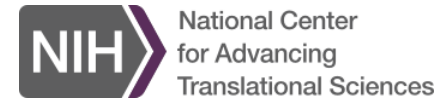
Patricia Greenberg, Manager & Biostatistician

Tracy Andrews, Biostatistician

Student assistants
    Currently:
    Natale Mazzaferro
    Brielle Formanowski
    Meizhen Yao

    Previously:
    Weiyi Xia
    Radhika Trivedi

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BERD Original Aims
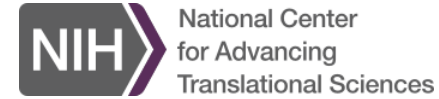
- Aim 1. Facilitate the translation of science into practice by providing easily accessible, state-of-the-art clinical study design and data analysis support.

- Aim 2. Promote the development, implementation and sharing of innovative study design and methods, including outcome measure development, biostatistics, epidemiology, and analysis of results.

- Aim 3. Provide educational opportunities for clinical and translational researchers to develop basic skills and understanding in study design and data analysis.

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BERD Progress to Date

BERD Navigator

- Online form

- Recorded in REDCap

- Initial response with 24h

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BERD Progress to Date

Study Support   **Over 100 Projects**

Schools   Behavioral Health/Psych; Criminal Justice; Dental
                        Medicine; Nursing; Pharmacy; Public Health;
Social   Work; RWJ Medical School; NJ Medical School/
                        University Hospital; RWJ Barnabas/St
Peter's Hospitals

Clinical Dept   Family Medicine; Medicine; Obstetrics &
Gynecology;   Ophthalmology; Orthopedic
Medicine/Surgery;   Pathology; Pediatrics;
Pulmonary/Rehab; New Jersey Alliance for Clinical and Translational Science
        Trauma/Surgery

BERD Progress to Date
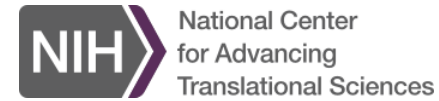
Example: BERD Support on COVID-19 Research

Rutgers Coronavirus Cohort Study

RWJ Screening Study

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BERD Progress to Date

Aim 2: Promote innovative methods development

- Mini-Methods Grant Program
    - 4 Funded
    - Current call for applications

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BERD Progress to Date
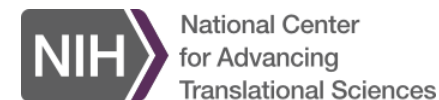
Mini-Methods Grant Recipients

Wei (Vivian) Li, Assistant Professor of Biostatistics, Rutgers SPH
"Understanding Cell type Specific Gene Regulatory Networks"

Suril Gohel, Assistant Professor, School or Health Professions, Rutgers
"Towards Development of Stable Multimodal Neuroimaging Based Markers of AD Progression"
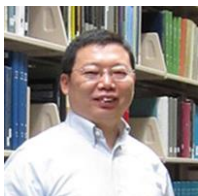
Yaqun Wang, Assistant Professor of Biostatistics, Rutgers SPH
"New Statistical Models for Cancer Precision Medicine Studies with PDX Trial"
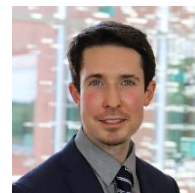
Mark McGovern, Assistant Professor, Rutgers SPH
"How common are missing data in HIV RCTs and how is the problem handled? Gathering preliminary data to assess the consequences of assuming missing at random"

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BERD Progress to Date
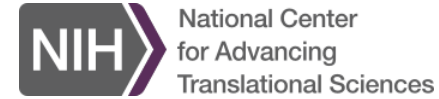
Aim 3: Education

- Workshops on design and analysis
  - In person, live broadcast, recorded and available on Canvas
- 5 workshops to date
- Qualtrics survey after each

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BERD Progress to Date
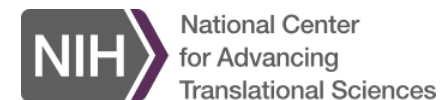
Canvas Page

- 389 people enrolled

NJActs Website

Setting the Stage: An Introduction to Biostatistics and Epidemiology for Researchers

Introductory Statistics for Clinical Researchers 11/07/19

Epidemiology: Introduction and Key Concepts 11/07/19

Statistical Design Considerations for Randomized and Exploratory Clinical Trials

Statistical Design Considerations for Randomized and Exploratory Clinical Trials 11/19/19

Best Practices in Data Management for Researchers

Best Practices in Data Management for Researchers 12/13/19

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Future Plans

Ways to access support

- Standard portal

- Microsoft Teams (quick questions)

New workshops

- Adaptive trials; R & R shiny; more

Expand team

- Support more projects

- Provide more data capture and management support (REDCap)

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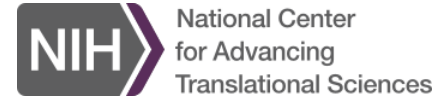
Thank you!

2020-2021 PROGRESS and PLANS
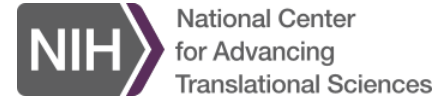
Regulatory Knowledge and Support Core

2020 NJ ACTS Retreat
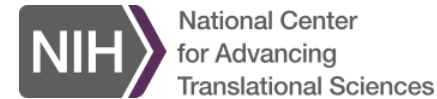
November 13, 2020

New Jersey Alliance for Clinical and Translational Science

Regulatory Knowledge and Support
Lead and Co-lead

Céline Gélinas, PhD

Senior Associate Dean for Research

Professor and Chair, Biochemistry and Molecular Biology

Rutgers, Robert Wood Johnson Medical School

Judith Neubauer, PhD

Professor of Medicine, Division Pulmonary & Critical Care
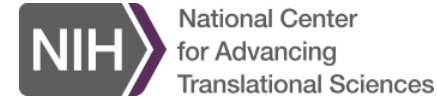
Rutgers, Robert Wood Johnson Medical School

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2020-2021 PROGRESS and PLANS

Accomplishments:

1) Developed an easy to use and logical navigation tool to support translational research

- Guides and educates users re. Human Subjects Project Lifecycle

NJACTS website:

Investigator Resources

https://njacts.rbhs.rutgers.edu/investigator-resources/regulatory/

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New Jersey Alliance for Clinical and Translational Science

Home   About 3   Membership   Community 3   Investigator Resources 3   Education & Training 3   Contact Us

Home / Investigator Resources / Regulatory

INVESTIGATOR RESOURCES

Research with New Jersey

Clinical Research Units

Biostatistics & Epidemiology Services

L **Informatics Services**

Regulatory

Funding Opportunities

Special Populations in Research

ClinCard

COVID-19 Data Analytics Platform

Regulatory

The Regulatory Core offers regulatory and quality assurance support in all aspects of clinical research from preclinical requirements to first-in-human studies and beyond. The goal is to provide the NJACTS community with the tools, training and support needed to navigate the complex regulatory pathways that accompany translational research.

| Is my project "Human Subjects Research"? | ⊕ |

| Before You Start: Special Considerations | ⊕ |

| Human Subject Project Lifecycle | ⊕ |

Go to Clinical Research Units

Go to Rutgers Institutional Review Boards (IRB)

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Regulatory

The Regulatory Core offers regulatory and quality assurance support in all aspects of clinical research from preclinical requirements to first-in-human studies and beyond. The goal is to provide the NJACTS community with the tools, training and support needed to navigate the complex regulatory pathways that accompany translational research.

Is my project "Human Subjects Research"?   ⊝

Human subjects research may include field work, humanities, social-behavioral, and/or biomedical research. Not all research with human subjects, however, meets the legal and University threshold for requiring IRB review.

To determine if a project qualifies as "human subjects research", answer questions A & B

A) Does my project involve *Human Subjects*?
Human subject means a **living individual about whom** an investigator conducting research obtains:

1. Data or **biospecimens** through **intervention** or **interaction** with the individual
2. **Identifiable private information**

B) Is my project *Research*?
Research is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge". Is it an activity designed to test a hypothesis [and] permit conclusions to be drawn through a formal study plan with a set of procedures to reach an objective? If yes, it is ***research***.

You can use this quick and easy-to-use **Human Subjects Determination Tool** to help you determine whether your study requires IRB review.

If you require more information than offered by the quick tool, you can find additional guidance on when research requires IRB review:
Am I Doing Human Subjects Research?
Does my study require IRB approval?

You may also call and consult the **IRB office**

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NJacts

INVESTIGATOR RESOURCES

Research with New Jersey

Clinical Research Units

Biostatistics & Epidemiology Services

L **Informatics Services**

Regulatory

Funding Opportunities

Special Populations in Research

ClinCard

COVID-19 Data Analytics Platform

Regulatory

The Regulatory Core offers regulatory and quality assurance support in all aspects of clinical research from preclinical requirements to first-in-human studies and beyond. The goal is to provide the NJACTS community with the tools, training and support needed to navigate the complex regulatory pathways that accompany translational research.

Is my project "Human Subjects Research"?   ⊕

Before You Start: Special Considerations   ⊕

Human Subject Project Lifecycle   ⊖

I	Activities for Preparatory Research
II	Feasibility
III	Getting Started: Building the IRB Protocol
IV	Choose Appropriate IRB Application
V	Consider Special Study Requirements
VI	Study Personnel and Training
VII	Recruitment Materials and Informed Consent Documents
VIII	Plan for IRB Review
IX	Confidential Disclosure and Clinical Trial Agreements
X	Clinical Trials.gov
XI	Study Closure and Data Retention

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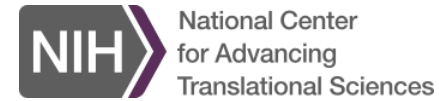
Choose Appropriate IRB Research Protocol

Depending on the type of research conducted, the PI completes one of the following **Research Protocols**:

Interventional Research Protocol – used by biomedical and social-behavioral researchers conducting research in which subjects are assigned to receive one or more interventions to evaluate their effects (e.g. clinical trials, CBT, Behavioral Modification studies, or randomized outcome studies).

Non-Interventional Research Protocol – used by social-behavioral and biomedical researchers for any research involving various types of interactional or observational methodologies: observations, interviews, focus groups, surveys, program evaluations, quality of life or interactional research.

Secondary Research with Data or Biospecimens Protocol – studies involving use of retrospective or archival data (including materials or specimens). Secondary research with data—which may include written text, images or audio-/visual-recordings—or biospecimens that were or will be collected for other purposes.

Local Context Supplement – for use when collaborating with another institution(s) leading the research project.
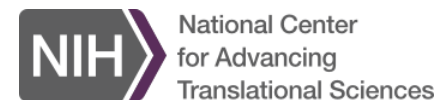
Data/Tissue Repository SOP – for use in establishing a tissue or data bank (repository).

NIH Clinical Trial Protocol and NIH Behavioral and Social Research Protocol templates are also available on this IRB site.

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Plan for IRB Review

Does your study qualify as human subject research? Use the algorithm for **Non-Human Determination, HSP-310- Worksheet** to find out.

You can also use this quick and easy-to-use **Human Subjects Determination Tool** can aid you in determining whether your study requires IRB review.

All protocols are submitted in eIRB – find out **How to Submit**

Human subject research will receive either a **Convened Board** or **administrative** (**Exempt** or **Expedited**) review depending on the type of research proposed.

Exempt studies, in general, utilize surveys, observational, or deidentified data and must fall within the **8 categories that are *exempt*** from the other provisions of the regulations. **Exempt** submissions are reviewed when they are received in **eIRB**

Expedited review means that the review can be completed by a qualified IRB reviewer and that it satisfies two main criteria: the study must be minimal risk and falls into one of the **9 categories established by the regulations**. Submissions are reviewed when received in **eIRB**.

Full Convened Board review must be used for the initial review of all studies that are not eligible for expedited review or exemption, and research involving prisoners. **Submission deadlines and IRB meeting dates**.

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2020-2021 PROGRESS and PLANS
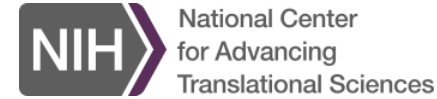
Plans to service NJ ACTS community and address community needs:

- **beta test** with both seasoned and novice IRB users
- **add links** on the IRB, RBHS research and schools/institutions research websites
- **broad announcement** of new regulatory resource across NJ ACTS, and then CTSA consortium
- **incorporate tracking** to inform improvements, and identify educational/training needs

  - **User feedback**: What were you unable to find? How can we improve?
  - **User title**   [student, resident, fellow, staff, assistant/associate/full professor, other]
  - **Department, School, Institution**
  - **Rutgers, NJ ACTS or CTSA consortium**

- make it an interactive tool by including a "Chat with an Expert" dialog box to enhance user experience in real time

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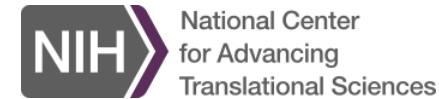
Accomplishments:

2) Integrating Regulatory Affairs as part of the RBHS Clinical Trials Office
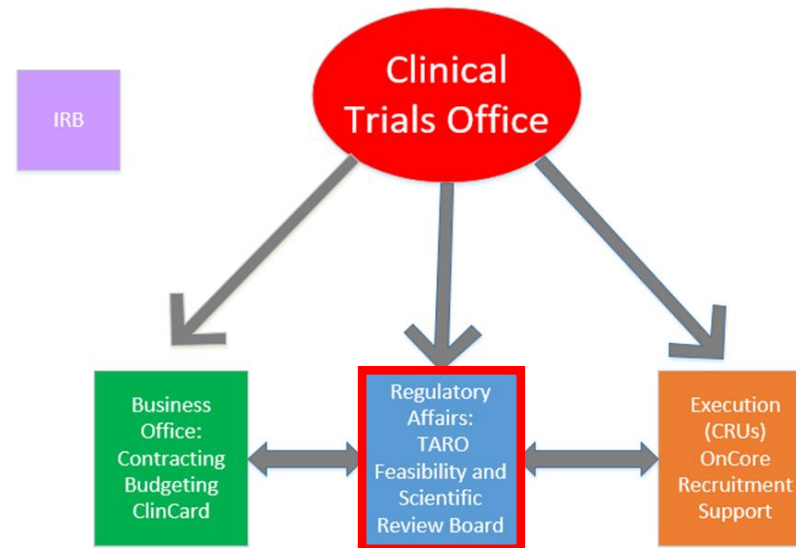
New Jersey Alliance for Clinical and Translational Science

2020-2021 PROGRESS and PLANS
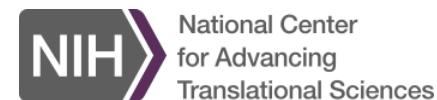
- **Challenge:** Sufficient funding to hire a qualified CTO Regulatory Manager (part-time)
- Conduct Exempt Reviews, under the auspices of the SRB
- Decrease turnaround time for exempt approvals
- Increase efficiency within the IRB
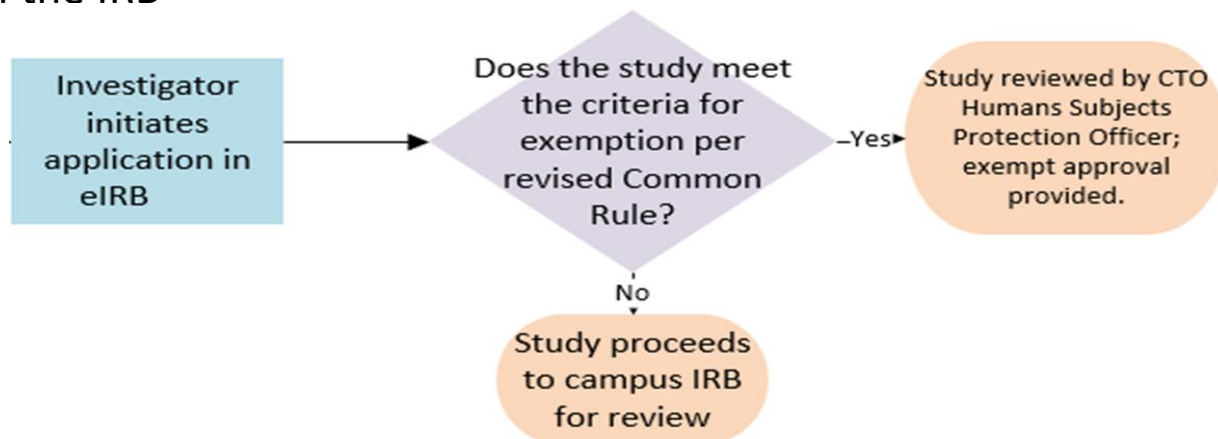
Investigator initiates application in eIRB → Does the study meet the criteria for exemption per revised Common Rule? —Yes→ Study reviewed by CTO Humans Subjects Protection Officer; exempt approval provided.

No ↓

Study proceeds to campus IRB for review

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Regulatory Knowledge and Support
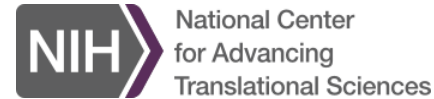
Metrics

- **Number of Navigation tool access** (at Rutgers, across NJ ACTS, eventually across CTSA consortium)

- **Topics most frequently accessed** (at Rutgers, across NJ ACTS, CTSA consortium)

- **Median IRB Review Duration** (Time from IRB submission to IRB approval) [For Investigator-initiated studies]
  - Current
  - After implementation of Interactive Navigation Tool
  - After implementation of Exempt Review through CTO
  - After implementation of both Exempt and Minimal Risk Expedited Review through CTO

- **Number of clinical trials registered in ClinicalTrials.gov**

- **Number of studies in non-compliance** with registering or submitting study results in ClinicalTrials.gov

- **Number of "Chat with an Expert" consultations** (at Rutgers, and across NJ ACTS, CTSA consortium)

New Jersey Alliance for Clinical and Translational Science

Core Interactions: Collaborations and Activities

	Informatics	Community	Team Science	Workfroce	Pilots	BERD	Regulatory	Special Pops	PCI/LTIC/A1LRIC	Biomarkers	Machine Learning	TL1	KL2
Informatics	■												
Community		■											
Team Science			■										
Workdorce				■			■						
Pilots					■								
BERD						■							
Regulatory							■						
Special Pops								■					
PCI/LTIC/LRIC							■		■				
Biomarkers										■			
Machine Learning											■		
TL1												■	
KL2													■

Nancy Reilly, RN, MS, CCRC, CHRC
Barbara Tafuto, MLS PhD
Pamela Dahlen

Regulatory Knowledge and Support
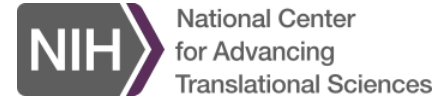
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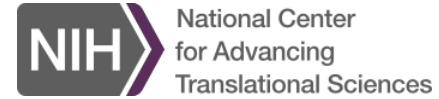
2020 NJ ACTS Retreat

November 13, 2020

Integrating Special Populations

New Jersey Alliance for Clinical and Translational Science

Integrating Special Populations Leadership

Stephen Crystal, Board of Governors Professor, Institute for Health, Health Care Policy, and Aging Research

Olga Jarrín Montaner, Assistant Professor, School of Nursing and Institute for Health, Health Care Policy, and Aging Research

Panos Georgopoulos, Professor, Environmental and Occupational Health Sciences Institute, School of Public Health

Johannes Haushofer, Assistant Professor, Psychology and Public Affairs, Princeton

Rusty Reeves, Professor, Director of Psychiatry, Forensic Psychiatry Training Director, University Behavioral Health Care

ISP Updates

- Dataset Development
- Scholar Mentoring
- Consultations
- Project Updates
- Next Steps

Dataset Development

Service Aim: Serve the development and expansion of large dataset research on SPs by utilizing the Core's expertise to provide the most up to date integrated big healthcare data for use by investigators

- Completed acquisition, organization and upload of 2008-2016 Medicare-NDI dataset with 100% match to NDI. Dataset is being used in current and planned studies on multiple SPs (elderly, HIV, SMI, disability) by investigators from multiple Rutgers units, and in collaborations with external partners. Consultations underway with SPH investigators on study of elderly suicide using these data; used in S. Shiau K (HIV).

- 2018 national Medicare-Part D (50%) received and integrated into database.

- Proposal for enhancements of NJ Medicaid database held at Rutgers to include mortality and prescriber data; achieved approval in concept from DMAHS leadership.

Dataset Development

Service Aim: Serve the development and expansion of large dataset research on SPs by utilizing the Core's expertise to provide the most up to date integrated big healthcare data for use by investigators

- Reviewed, prioritized, selected 700+ community variables for linkage with 50% Medicare/Part D dataset 2008-2018 (from AHRF, Harvard Public Health Disparities Geocoding Project, etc.). Created linked dataset being used by investigators on multiple topics. SP workshop planned to brief potential users on claims-community dataset.

- Completed check and integration of 2013 CMS Medicaid data into national Medicaid dataset. Progress toward updating through 2018 by mid-2021. Data completeness analyses for Medicaid dataset.

- DOH IRB for Linkage of DOC/DOH data on re-entry population.

Scholar Mentoring
Service Aim: Providing mentorship to early career investigators conducting research on special populations

- Qiana Brown (KL2): Mentorship on research on SUD during pregnancy; co-I on NJ-ACTS U01 (Einstein et al) w/Northwestern (Well Mama Action Hub). Developing R-01 using linked Medicare data on disability population.

- Stephanie Shiau (K01): ISP analysts helped link datasets for K01 submission, research on aging and individuals with HIV. Mentoring on K award; being brought forward for funding December 2020.

- Jennifer Miles (TL1 Fellow).

- Amesika Nyaku (K01): Submission to NJ ACTS Society of Scholars (Crystal mentorship); K award application submitted, review Nov. 2020.

- Mark Van Der Maas (KL2): Gambling use disorder.

- Hannay Szlyk: ISP support on research on suicide in youth.

- Elizabeth Luth: Submission of application to NJ ACTS Society of Scholars

Navigation Consultations

Service Aim: To provide technical expertise and mentorship, leading to further research in special populations

- Provided consultations with individuals from the following groups to provide guidance, make new connections, and establish new collaborations.
  - Rutgers Cancer Institute, Rutgers School of Public Health, Rutgers School of Social Work, Johns Hopkins University, UCSD, Emergency Medicine/NJMS, Columbia University, Michigan State

- Topics include:
  - Aging/Geriatrics, Justice-involved populations, OUD/SUD, COVID-19, Alcohol Use Disorder, Racial/Ethnic minorities

	SSW	SPH	NJMS	Family Medicine	Cancer Institute	Columbia	Johns Hopkins	UPENN	UCSD	Camden Coalition	COE
Elderly		x		x	x			x	x		
Youth	x	x									
SMI	x	x				x					
Substance Use	x		x			x	x			x	x
HIV/ Inf. Disease		x	x								
Disparities & Health Equity	x		x	x					x	x	
Health Policy							x				
Emergency Medicine			x								
Suicide		x									
Medication Safety		x							x		

Topics of Consultations

Special Populations Topic	Count*
Aging	6
Addiction	4
Youth	2
Mental Illness	4
Underserved Populations	2
Infectious Disease	2
Training Award Development or Training Activities	6

Public and Stakeholder Development
Service Aim: To inform key stakeholders, policy makers, and others of new developments within special populations research

- Partnership with Hopkins, VOA, Bloomberg to assess emergency COVID release of 20% of NJ prisoners and support state efforts to improve prison re-entry.

- Development of multi-stakeholder collaborative on harm reduction in NJ with Camden Coalition.

- Testimony to NJ Senate Health Committee on proposed legislation for expanding harm reduction services in NJ.

- Symposium on Covid-19's Impact on Substance Use Disorder Treatment and Services, 10/16/20 organized by CHSP and SP core (more than 200 participants). NJ policy, treatment system and community stakeholders identified and invited to panels.

Projects

- Workforce Development Fall 2020 Intern
  - Project Title: "Development of Marketing Materials for Integrating Special Populations Core"
  - **Service Aim: The intern is tasked with the development of marketing and promotional tools to promote the services of the Integrating Special Populations (ISP) Core. Tools will be utilized to inform and attract scholars inside and outside of Rutgers of available consultative and analytic services provided by the Core leads and staff.**
- Environment Health Symposium
  - Delayed due to COVID; Planned for a half day virtual symposium
  - **Service Aim: To provide up to date information on the COVID-19 pandemic and its impact on special populations**
- Engaging Camden Coalition and others in development of integrated care model for Medicaid participants with OUD in NJ
  - **Service Aim: Think-tank meetings to develop stakeholder consensus on envisioning a more-comprehensive service delivery model for the state to inform policy and program development in the state.**
- Webinar on work with criminal justice involved population
  - **Service Aim: To provide important evidence regarding key issues facing NJ as a result of recent COVID-19 related early release program**
- Workshop on linking Medicare data with community data on exposures/resources/social determinants.
- Webinar series geared toward graduate level/early investigators
  - **Service Aim: To provide an overview and information on existing resources that may be used by early stage investigators interested in special populations research**

2020-2021 PROGRESS and PLANS

Service Goals: How has the Core served NJACTS and the CTSA Consortium to establish new collaborations and provide access to instruments/tools for translational research? How has the Core established success?

Overview of Service Plans for Year 3:

- Use of marketing materials developed with WFD Intern

- Provide additional consultations

- Continued mentorship (existing and new)

- Establish more formal collaborations with Cores (ex. Community Engagement, Informatics)

- Make connections with other CTSA Hubs

Pilot Translational and Clinical Studies Program
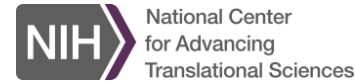
New Jersey Alliance for Clinical and Translational Science
http://njacts.rbhs.rutgers.edu

An NCATS-funded CTSA Hub: UL1 TR003017, KL2 TR003018, TL1 TR00301

RUTGERS
Institute for Translational Medicine and Science

PRINCETON UNIVERSITY

NJIT
New Jersey's Science & Technology University

Pilot Studies Co-Leads

Arnold Rabson, MD
Laura Gallagher Chair of
Developmental Biology and
Director, The Child Health Institute
of New Jersey and
Professor of Pharmacology;
Pediatrics, and Pathology and
Laboratory Medicine;
Rutgers Robert Wood Johnson
Medical School

Reggie Caudill, PhD
Panasonic Chair of
Sustainability, Martin
Tuchman School of
Management
New Jersey Institute of
Technology

Samuel Wang, PhD
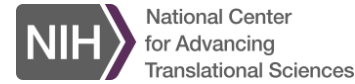Professor
Neuroscience Institute
Princeton University

Guiling (Grace) Wang, PhD
Professor
Associate Dean for
Research
The Ying Wu College of
Computing
New Jersey Institute of
Technology

New Jersey Alliance for Clinical and Translational Science

Pilot Program Management Committee Members

Name	School	Institution
Rafael Benoliel, BDS	School of Dental Medicine	Rutgers
Linda Brzustowicz, MD	School of Arts and Sciences	Rutgers
Pamela de Cordova, PhD, RN-BC	School of Nursing	Rutgers
Kenneth Gill, PhD	School of Health Professions	Rutgers
Nicole Fahrenfeld, PhD	School of Engineering	Rutgers
Mark Pierce, PhD	School of Engineering	Rutgers
Debra Laskin, PhD	Ernest Mario School of Pharmacy	Rutgers
Jeffrey Laskin, PhD	School of Public Health	Rutgers
Mark Brynildsen, PhD	Chemical Engineering	Princeton
Noreen Goldman, D.Sc	Woodrow Wilson School	Princeton
Abby Notterman, JD, MBE	Bioethics	Princeton
Zemer Gitai, PhD	Molecular Biology	Princeton
Kevin Belfield,PhD	Science and Liberal Arts	NJIT
Bryan Pfister, PhD	School of Engineering	NJIT

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Aims of the Pilot Program
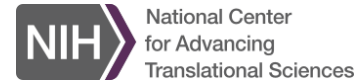
- Advance team research to promote novel approaches and methodologies in translational medicine and science

- Foster interdisciplinary research that leverages in-kind partner support to generate or test novel hypotheses

- Seed collaborations between the NJ ACTS partners

- Inspire new methodologies to evaluate and to assess NJ ACTS/CTSA Hub processes to improve outcomes

New Jersey Alliance for Clinical and Translational Science

Year 1 and Year 2 Funding Categories
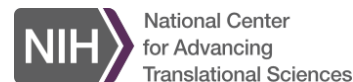
Pilot Grant Program	Maximum Budget Request	Estimated Number of Awards	Are Collaborator or Partners Required?	Collaborators/Partners	Year 2 Deadline
Translational and Clinical Sciences Award	$60,000/Yr 1 $110,000/Yr 2	3	Required	Two or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	May 1, 2021
Methodological and Infrastructure Awards	$40,000	2	Required	Two or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	May 1, 2021
Propel Awards	$20,000	2	Preferred	Two or more NJ ACTS Institutions: Rutgers, NJIT or Princeton	May 1, 2021
Valued Partnership Awards	$25,000/Yr 1 $50,000/Yr 2	2	Required	Industry, government, community organizations, insurance companies, other CTSA Hubs	May 1, 2021
Novel Approaches to Evaluation and Benchmarks of CTSA Hubs	$25,000	2	Preferred	Other CTSA Hubs	May 1, 2021

New Jersey Alliance for Clinical and Translational Science

Proposals/Awards by Institution: Yr. 1 (41.6 % success rate)
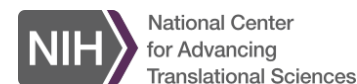
	Awards/Proposals	Rutgers	Princeton	NJIT
Translational and Clinical Sciences Award	4/9	4/9	2/3	2/6
Methodological and Infrastructure Awards	4/13	4/13	0/1	4/12
Propel Awards	1/1	1/1	1/1	0/0
Valued Partnerships	1/1		1/1	
Total	10/24	9/24	4/6	6/18

Proposals/Awards by Institution: Yr. 2 (53.3 % success rate)

	Awards/Proposals	Rutgers	Princeton	NJIT
Translational and Clinical Science Awards	4/11	4/11	3/6	1/5
Methodological and Infrastructure Awards	1/1	1/1	0/0	1/1
Propel Awards	1/1	0/0	0/0	1/1
Value Partnership Awards	1/1	0/0	1/1	0/0
Novel Approaches Awards	1/1	1/1	0/0	0/0
Total	8/15	6/13	4/7	3/7

New Jersey Alliance for Clinical and Translational Science

Distribution by Gender – Year 1

	Male	**Female**	**Total PIs**
Proposals	42 (76%)	13 (24%)	55
Awards	15 (75%)	5 (25%)	20

Distribution by Gender – Year 2

	Male	**Female**	**Total PIs**
Proposals	23 (62%)	14 (38%)	37
Awards	10 (53%)	9 (47%)	19

New Jersey Alliance for Clinical and Translational Science

Year 1 – Distribution within Universities

Princeton Submissions
■ Translational

- Woodrow Wilson…
- Molecular Biology
- Neuroscience Institute
- Lewis Sigler Inst for…

0 0.5 1 1.5 2 2.5

NJIT Submissions
■ Translational

- Science and Liberal Arts
- College of Engineering
- Wu College of…
- Tuchman School of…

0 5 10 15

Rutgers Submissions
■ Translational
■ Method

- School of Dental…
- Arts and Sciences
- CINJ
- SHP

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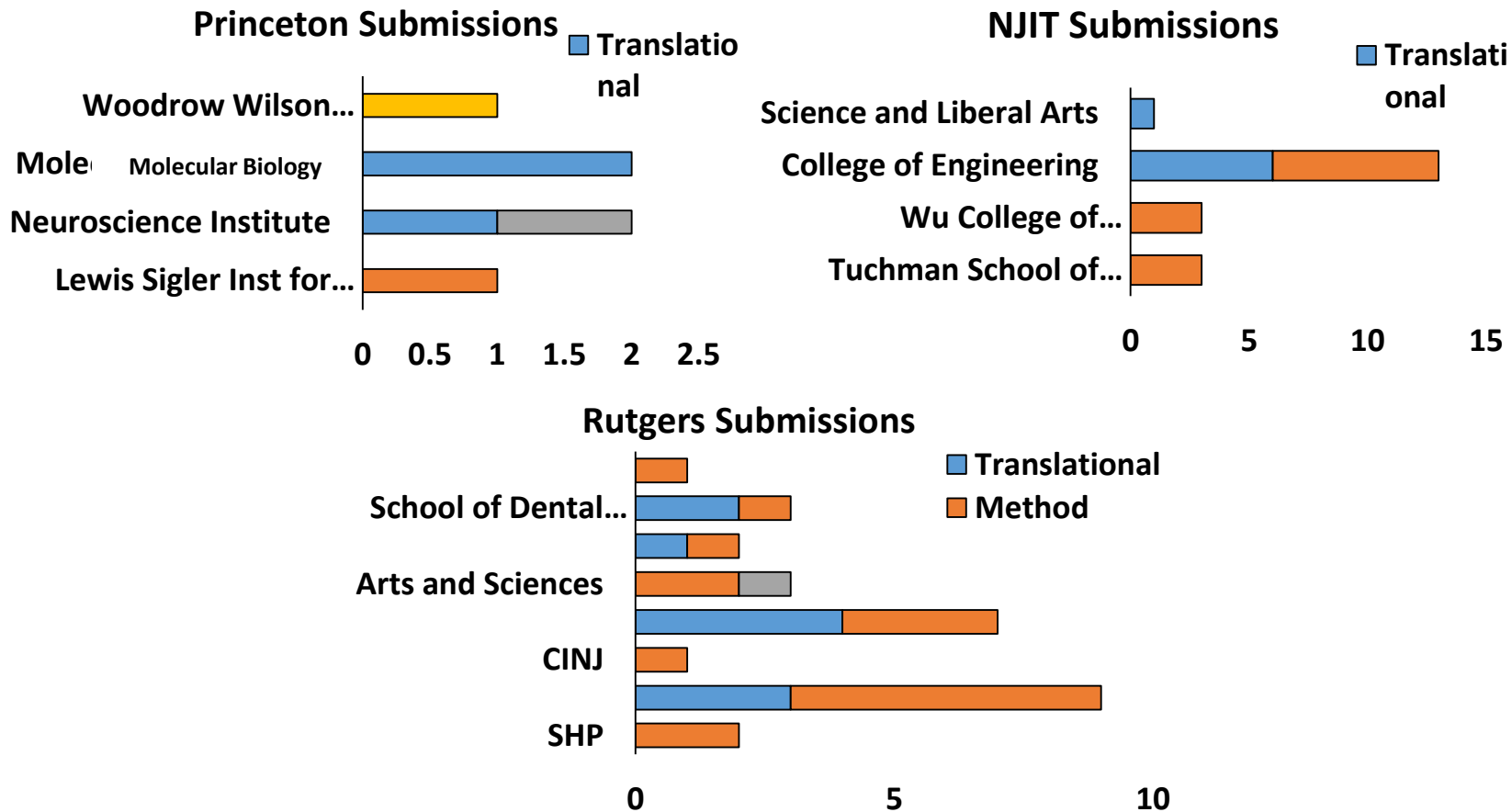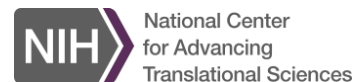
New Jersey Alliance for Clinical and Translational Science

Year 2 – Distribution within Universities

Rutgers Submissions

- SHP
- SEBS
- Engineering
- RWJMS
- NJMS

Legend: ■ Clinical and Translational ■ Methodological

NJIT Submissions

- College of Science
- Engineering

Legend: ■ Clinical and Translational ■ Methodological

Princeton Submissions

- Chemistry
- Engineering
- Psychology
- Molecular Biology
- Ecology and…
- Neuroscience

Legend: ■ Clinical and Translational ■ Methodological
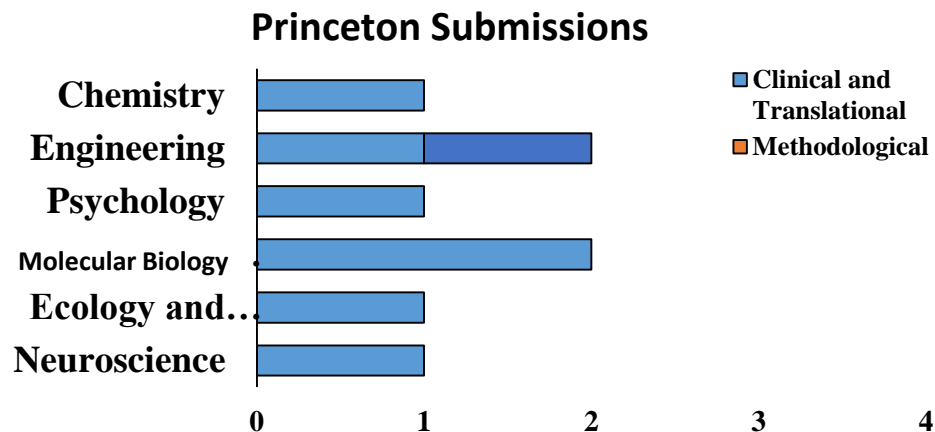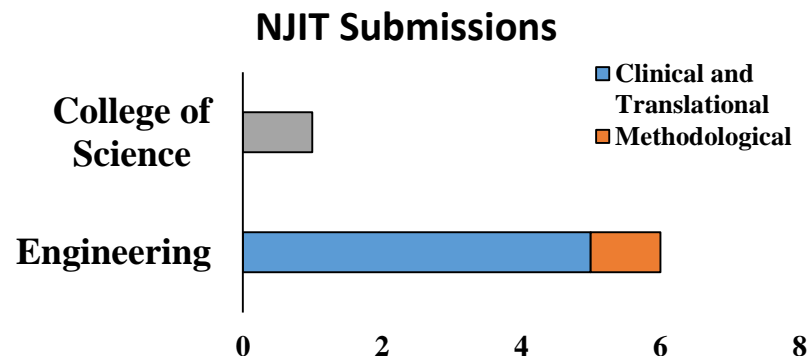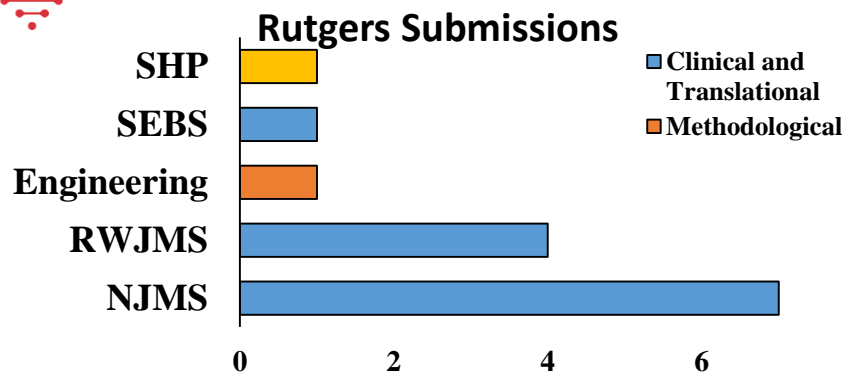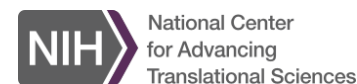
New Jersey Alliance for Clinical and Translational Science

Year 1 Awards: Clinical and Translational

"Development of new long-acting local anesthetics and its application in chronic pain" Xiaoyang Xu (NJIT) and Yuanxiang Tao (Rutgers)

"Structural and functional mapping of islet β-cell sensory innervation" Abdelfattah El Ouaamari (Rutgers) and Esteban Engel (Princeton)

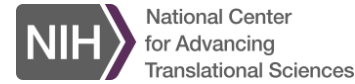"A dynamic functional splint to restore hand function in children with cerebral palsy" Alice Chu (Rutgers) and Saikat Pal (NJIT)

"A FRET-based HTS to identify antibacterial drug leads targeting ternary complex formation in E.coli" Emanuel Goldman (Rutgers), Zemer Gitai (Princeton) and Wlodek Mandecki (Rutgers)

New Jersey Alliance for Clinical and Translational Science

Year 1 Awards: Propel & Valued Partner

Propel:

"Pain as a trigger for opioid dependence in the context of epigenetic susceptibility" David J. Barker (Rutgers) and Catherine Jensen Peña (Princeton)
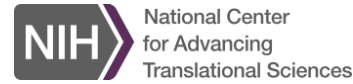
Valued Partner:

"Housing and Health in New Jersey's Capital City" Kathryn Edin and Sara Gold (Princeton)

New Jersey Alliance for Clinical and Translational Science

Year 1 Awards: Methodological and Infrastructure

"Remote evaluation of upper extremity motor control" Gerard Fluet (Rutgers) and Sergei Adamovich (NJIT)

"Leveraging functional near infrared spectroscopy for auditory brain health" Antje Ihlefeld (NJIT) and Yu-Lan Mary Ying (Rutgers)

"A natural language processing platform for automated information extraction from EHR's for clinical decision support and investigative research" Yi Chen (NJIT) and David Foran (Rutgers)

"Apply natural language processing and deep learning to EMR management, preprocessing and decision making" Dantong Yu (NJIT), Xinyue Ye (NJIT) and Yaqun Wang (Rutgers)

New Jersey Alliance for Clinical and Translational Science

Year 2 Awards: Clinical and Translational
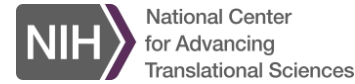
"Angiogenic peptide hydrogel for cardiac repair"
Eun Jung Lee (NJIT), Vivek Kumar (NJIT) Dominic Del Re (Rutgers)

"Motivation for cognitive and physical effort in depression"
Jonathan Cohen (Princeton), Anna Konova (Rutgers), Laura Bustamante (Princeton)

"Improving mouse models of lung defense: neutrophil-mediated parasite resistance, tissue damage and repair"
Andrea Graham (Princeton), William Gause (Rutgers)

"Developing a longitudinal cohort of transgender youth to access health and wellbeing through physical, psychological, and molecular assessment"
Daniel Notterman (Princeton), Ian Marshall (Rutgers), Kristina Olson (Princeton)

New Jersey Alliance for Clinical and Translational Science

Year 2 Awards: Propel & Valued Partner
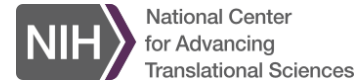
Propel
"Mechanisms of Medical Image Perception in Radiologists"
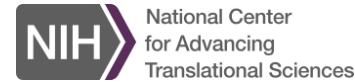Yelda Semizer (NJIT)

Valued Partnership
 "Aerosol Production of Bacteriophage Formulations from Submicron Droplets for Biomedical and Pharmaceutical Applications"
Howard Stone (Princeton), Mohamed Labib (NovaFlux)

New Jersey Alliance for Clinical and Translational Science

Year 2 Awards: Methodological and Infrastructure & Novel Approaches

Methodological and Infrastructure
 "A Microfluidics Technology for Non-Sacrificial Analysis of Biomaterial Implants In Vivo"
Roman Voronov (NJIT), Joseph Freeman (Rutgers)
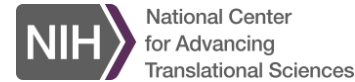
Novel Approaches

"CTSA Hub Website Database and Search Engine"

Barbara Tafuto (Rutgers), Riddhi Vyas (Rutgers), Trish Pruis (OHSU)

New Jersey Alliance for Clinical and Translational Science

Maximizing Success

Overarching goals:

- Respond to the needs of the NJ ACTS scientific community
- Provide efficient, fair, and helpful reviews
- **Maximize the long-term impact of the pilots (NIH grants, publications)**

Continuing evaluation:

- Procedures: Timing of RFA; Letter of intent; Pre-submission Workshop
- Categories: Adjust based on proposals in Year 1-2; Consider change to evaluation/cross Hub scientific projects; Targeted RFA v more general
- Review Process: Avoidance of conflicts of interest; Reviewer Pool; Role of the Pilot Program Management Committee

New Jersey Alliance for Clinical and Translational Science

Maximizing Success
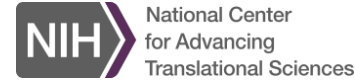
Opportunity: How to increase interactions across NJ ACTS partners?
- Increasing knowledge of expertise available at different partners

For Your Consideration – For Year 4 and Beyond:

An NJ ACTS Scientific Symposium
- Work with Team Science to plan sessions at scientific symposium
- Develop subgroups around targeted topics

New Jersey Alliance for Clinical and Translational Science

New Jersey Alliance for Clinical and Translational Science

Advancing clinical and translational science to develop new therapies and treatments and improve health care

NJACTS FELLOWS PROGRAM (TL1)
For predoctoral and postdoctoral trainees

Kathleen Scotto, Program Director

Daniel Notterman, Co-Director
Anda Cytroen, Program Administrator
Wayne Zhou, Rutgers Liaison
Bianca Freda, Princeton Liaison

NJACTS Retreat November 13, 2020

NJ ACTS Fellows Program - Goals

- Enhance scientific knowledge, skills, and competencies needed to conduct translational and/or clinical research

- Provide career development activities beyond those encountered in traditional training programs, with an emphasis on application, communication, collaboration and team science.

- Impart a deep knowledge/understanding of the extensive research, professional and technical resources within NJ ACTS and the CTSA consortium, optimizing access to professional and networking opportunities.

-

NJ ACTS Fellows Program: Snapshot
Growth And Diversity Of Disciplines

- Competitive RFA yielded 6 fellows in 1st cohort (October 2019), 6 in second cohort (September 2020)

- Pilot program for medical student in collaboration with Workforce Core (Sept 2020)

- 7 Male; 6 Female

- 9 pre-docs, 4 postdocs

- 9 Ph.D., 3 MD-PhD, 1 MD

- Two first year fellows awarded individual fellowships (LoSchiavo, Yonk)

- Multidisciplinary cohort encompasses basic biomedical research, population behavioral and social sciences, and engineering.

- Academy of Mentors membership = 131 faculty

2019 NJACTS Fellows

Chloe Cavanaugh (predoctoral)
Mechanism and potential therapeutic inhibition of HCMV-induced telomerase activation (Notterman, Princeton)

"The training provided by the core curriculum grant writing and team science courses augment my communication and interpersonal skills to improve my ability as a scientist and educator."

Courtney McDermott (predoctoral)
Identification and functional assessment of mTOR and cytoskeletal pathways in idiopathic and 16p11.2 autism neural precursor cells (DiCicco-Bloom, Rutgers)

"The CTSA program will add value to my graduate training because it will challenge me to implement clinical and translational aspects into my research, which is critical for autism research that impacts affected individuals and families."

Bassel Ghadar (predoctoral)
Single cell genomic characterization of the pancreatic tumor and metastatic microenvironment and clinical associations (Ganesen, Rutgers)

"The opportunities and encounters I will have through the CTSA will not only help my PhD but will provide long term perspective and real-life examples of the careers physician-scientists can achieve."

2019 NJACTS Fellows (continued)

Caleb LoSchiavo (predoctoral)
Project: Human papillomavirus prevention, screening, knowledge, and risk among transgender individuals in New Jersey (Halkitis, Rutgers)

The education and skills I gain through the CTSA training program will support my ongoing research interests, allowing me to design and implement research programs focusing on sexual and gender minority health, the results of which will be translated into recommendations for evidence-based prevention, treatment, and policy interventions."

Alex Yonk (predoctoral)
Project: The role of POm in striatal circuitry modulation (Margolis, Rutgers)

"Movement disorders are a major health problem worldwide, yet the underlying neural circuitry is not well understood. I'm focused on investigating a thalamic input that modulates the mammalian striatum, a brain area crucial for sensorimotor integration and behavioral choice. I plan on using the experiences I gain in this program towards translating these fascinating basic research results in clinical settings, specifically towards movement disorders such as Parkinson's Disease and Huntington's Disease."

Tom Zajdel (postdoctoral)
Project: Programming cell migration for wound healing (Cohen, Princeton)

"As an engineer, it is essential to know the user that I am designing for and the CTSA program will provide this vital context about clinical practice."

2020 NJACTS Fellows

Ellen Acosta (predoctoral)
The spatiotemporal dynamics of the human skin microbiome in health and disease (Gitai, Princeton)

Andrew Boreland (predoctoral)
A Human Stem Cell-derived Brain Organoid Platform for HIV-1 Virus-Host Interactions (Pang, Rutgers)

Alexandra Burr (predoctoral)
A dynamic gene therapy for hypoparathyroidism (Parekkadan, Rutgers)

Jennifer Miles (postdoctoral)
Medication and Residential Treatment for NJ Medicaid Beneficiaries with Opioid Use Disorder: Implementing Evidence-based practices in Addiction Treatment (Crystal, Rutgers)

Susan Leggett (postdoctoral)
The effects of cell-level heterogeneity on cancer invasion and metastasis (Nelson, Princeton)
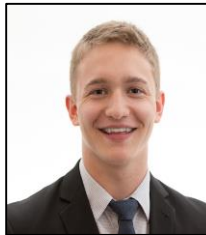
Camden MacDowell (postdoctoral)
Understanding Thalamic Control of Information Flow in the Brain and Mechanisms of Therapeutic Thalamic stimulation (Buschman, Princeton)

Shane Neibart, MD/MS Candidate, MS4
Non-Infectious Pneumonitis in Advanced Non-Small Cell Lung Cancer: Is There an Interaction Between Immune Checkpoint Inhibition and Radiotherapy? (Strom, Rutgers)

PRECISION TRAINING:
GOAL: To develop and enrich each fellow's knowledge, skills, and abilities as a translational scientist based on individual competencies and career objectives

CHARACTERISTICS OF A
TRANSLATIONAL SCIENTIST

BOUNDARY CROSSER

TEAM PLAYER

RIGOROUS RESEARCHER

PROCESS INNOVATOR

DOMAIN EXPERT

SKILLED COMMUNICATOR
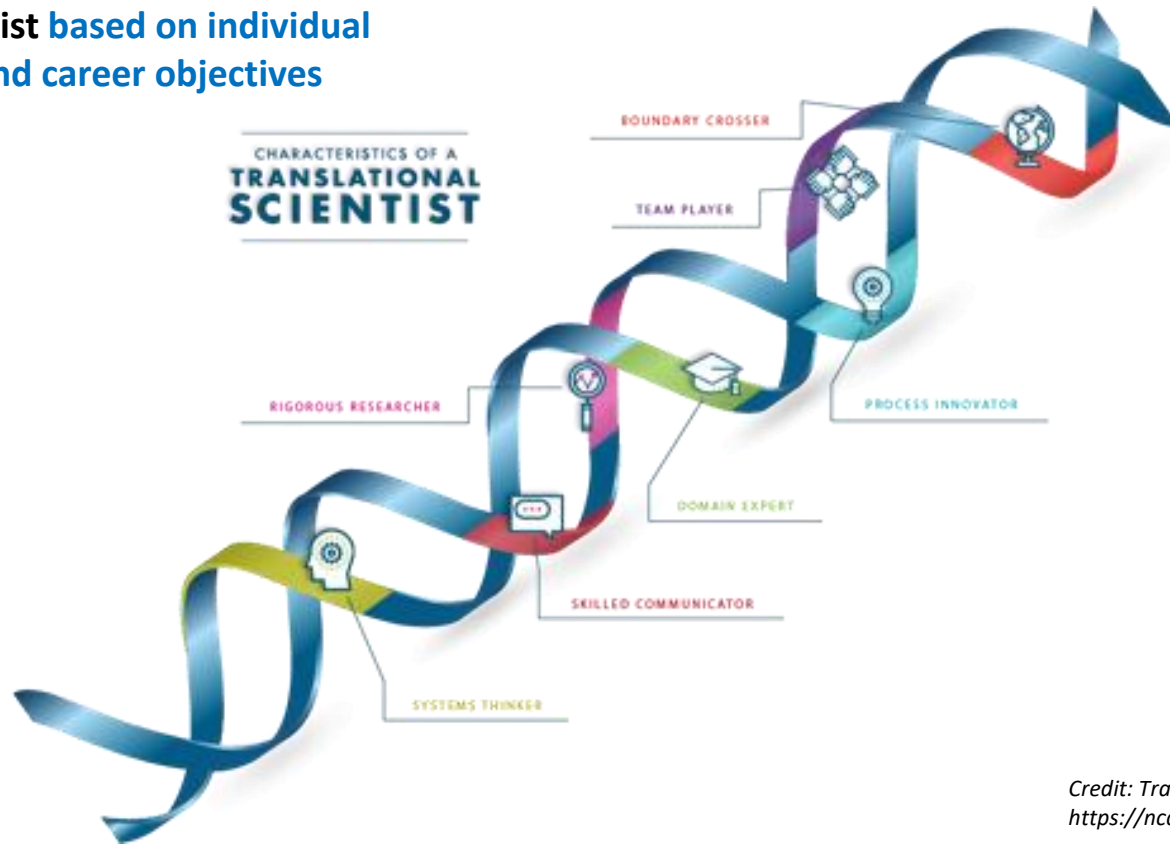
SYSTEMS THINKER

PRECISION TRAINING:
PROGRAM APPROACH

EXPLORING

MENTORING

IMPROVING SKILLS
Engagement/Experiential learning

- Design thinking
- Communication skills
- Implementation science
- Clinical shadowing
- Professional membership in discipline(s) of interest
- Team science: participation, leadership

BUILDING KNOWLEDGE

Basic Training
- Didactic training
- TS Self-assessment
- Online learning (CLIC, AAAS, etc)
- Journal clubs
- Guest speakers (SMEs, senior faculty, community advocates, e.g.)
- Workshops
- Fellows Seminar series

DEMONSTRATING ABILITIES

Application
- Integration of translational practice into primary research project
- Proposal writing
- Grant-seeking
- Team building
- Research presentation
- Badges, Certifications, Degrees

**CONNECTIN
G**

COMMUNICATING

ABC June 2020

COMPLEMENTARY SKILLS VALUABLE
FOR A TRANSLATIONAL SCIENTIST

Personal development

Resilience, agility, creativity, problem solving, leadership, negotiation skills, self-motivation, effective mentoring, career planning

Financial management

Understands financing of drug discovery and development; awareness of health economics, demonstrated understanding and application of IP protection, extramural funding budgeting

Time management

Determine priorities, allocate time and resources, work-life balance

Entrepreneurship

Seeks opportunities and possibilities for the development of commercial ideas, able to identify target population, understands marketplace considerations; demonstrates working knowledge of academic tech transfer

Project management

Knowledge of project management lifecycle, principles, agile doing, effective meeting management

Highlights: Year 2 Activities And Accomplishments

- ❖ Designed unique online assessment and planning tools to track individual, cohort, and program progress toward goals (self-assessment, mentor insights, precision training plan).

- ❖ Developed NJ ACTS Fellows guidebook outlining program requirements.

- ❖ Established training EAB (December 2020).

- ❖ Revised MS in Clinical/Translational Science Program (new clinical research track)

- ❖ Created new Team Science course (Spring 2021).

- ❖ Hosted monthly Fellow "dinners" with guest speakers (career paths, skills strength assessments, science communications, etc)

- ❖ Disseminated funding, workshop, seminar opportunities (including content from NJ ACTS, CLIC, Nature Careers…..)

- ❖ Engaged mentors with onboarding meeting and other planned activities

- ❖ Celebrated fellows' accomplishments (publications/presentations/grants)

Broadening Impact - Goals for Year 2

❖ Explore/implement digital badging and 'stacking' to demonstrate proficiencies, skills, and abilities

❖ Develop diversity and inclusion goals for both Academy and Fellow cohorts to broaden URM representation within program and raise visibility across available applicant pool

❖ Expand pilot program to professional degree candidates (nursing, pharmacy, etc.)

❖ Formalize Community of Practice for program applicants to continue engagement: disseminate learning opportunities – for small, select subset will provide more structured opportunities

❖ Further engage Academy of Mentors in programming and networking opportunities (mentor meet/greet planned for Winter 2021)

❖ Continue and expand participation in CTSA and related national workgroups:
  • Traveling TL1 Fellow inaugural program planning
  • Online Individual Development Plan Study (UPitt Hub)
  • Science of Team Science special interest group on team science competency assessment

Opportunities/Challenges

❖ Enhance engagement of NJIT/No applicants in Years 1&2

❖ Optimize policies and processes for inter-university courses/Current policies impede full access by fellows to all available resources.

❖ Enhance collaboration with UL1 Cores/Requires formal venues and plans that would accelerate coordination, optimize resources, and limit potential redundancy of effort

❖ Optimize website presence/Development has lagged, hampering efforts to raise visibility of program opportunities, achievements, program news, etc.

❖ Deep dive into resources available within CTSA consortium/centralized NJ ACTS resource database would optimize effort.

ENHANCING INTRA-NJ ACTS COLLABORATIONS

❖ **WORKFORCE:** Regular meetings, shared EAB, intern program

❖ **KL2:** Regular meeting, shared EAB, shared coursework/degree programs, Academy of Mentors

❖ **TEAM SCIENCE**: Program-required team science course co-directed by Team Science core team member (Parekkadan)

❖ **PROGRAM EVALUATION TEAM:** Regular meetings; coordination of quant/qual data for assessment and program feedback

❖ **COMMUNITY ENGAGEMENT/INFORMATICS/SPECIAL POPULATIONS/REGULATORY/BERD**.…: *G*uest speakers for Team Science course, Monthly fellow meetings, and Fellow seminars, Badging

❖ **SCHOOL OF COMMUNICATIONS/INFORMATION:** Seminars, Workshops

❖ **RUTGERS CENTER FOR ORGANIZATIONAL DEVELOPMENT:** Leadership training, Course development

QUESTIONS?
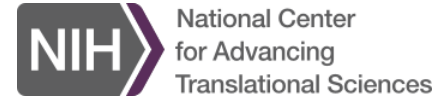
KL2 Institutional Career Development Program

2020 NJ ACTS Retreat
November 13, 2020
9:00 am - 3:00 pm

New Jersey Alliance for Clinical and Translational Science

KL2 Lead and Co-leads
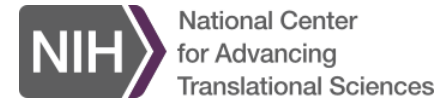
Sally Radovick, M.D.
Principal Investigator
Professor and Henry Rutgers Term Chair
Department of Pediatrics
Robert Wood Johnson Medical School

Daniel Notterman, M.D.
Training Core – Co-Director
Professor
Department of Molecular Biology
Princeton University

Stephen Vatner, M.D.
Training Core – Co-Director
Professor
Department of Cell Biology and Molecular Medicine
New Jersey Medical School

Fredric Wondisford, M.D.
Training Core – Co-Director
Professor and Henry Rutgers Term Chair
Department of Medicine
Robert Wood Johnson Medical School

New Jersey Alliance for Clinical and Translational Science

Our Current Scholars
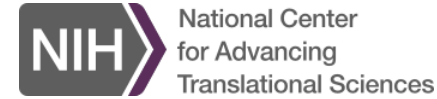
Our four scholars*; two are supported by institutional funds

- **Qiana Brown, PhD, MPH, LCSW**, Assistant Professor, School of Social Work (SOSW)
Mentor: Stephen Crystal, PhD, Board of Governors Professor, SOSW
  Cannabis use during preconception, pregnancy and lactation
- **Ankit Shah, MD**, Assistant Professor, Robert Wood Johnson Medical School (RWJMS)
Mentor: Fredric Wondisford, MD, Professor and Chair, Dept. of Medicine, RWJMS
  Glycerol contribution to hepatic gluconeogenesis in obesity
- **Chintan Dave, PharmD, PhD**, Assistant Professor, Ernest Mario College of Pharmacy
Mentor: Soko Setoguchi, MD, DrPH, Associate Professor of Medicine and Epidemiology
  Hypoglycemia and hyperglycemia associated with drugs used by older adults for diabetes
- **Elissa Kozlov, PhD**, Core Faculty, IHHCP and Aging Research; Instructor, School of Public Health
Mentor: XinQi Dong, MD, MPH, Director and Professor, IHHCP and Aging Research, RBHS
  Health mindfulness to alleviate stress for caregivers of cognitively impaired older adults

Chosen from a pool of 12 applicants

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS

How has the Core contributed to career development for KL2 and TL1 awardees, and to Workforce development?

PROGRESS:

We continue to strengthen our curriculum and collaborations with sponsors as listed below:

- Core Curriculum and sponsor:

   1. Responsible conduct in research - Rutgers Biomedical and Health Sciences (RBHS)

   *2. Biostatistics, Epidemiology – Rutgers University Biostatics & Epidemiology Services (RUBIES)

   *3. Grant writing programs – Institute for Health, Health Care Policy and Aging Research (IFH)

   4. Innovation and Entrepreneurship – Rutgers Office for Research and Economic Development (ORED)

   *5. Bioethics - RBHS

   6. Rigor and Reproducibility in Science - RBHS

   *7. Scientific writing-Rutgers University

   8. Rutgers Institute for Translational Medical Sciences (RITMS) Seminars

   9. Seminars in Translational Research - KL2 Core

   10. NJ ACTS Retreat – Oral presentation

   *11. IRB and IACUC Sessions - RBHS and ORED

*KL2 Scholar may be exempt

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS
KL2 Scholars' Highlights

Scholar name	Publications # 1st /middle author/ submitted	Grants submitted/ future submission	Oral presentations	Other
Qiana Brown, PhD*/**	2/1/4	R01 10/20	2	• NIH R25 LEAD fellowship • CTSA travel award –Un Meeting: Lifespan and Lifecourse Research • Editorial board member • Award Recipient: NIH Loan Repayment Program • CLIC KL2-PI Directors Group Visitors Scholars Program: Johns Hopkins CATAList Seminar Series: 11/3/20
Ankit Shah, MD	1/1/2	NJHF, not funded K23 6/20	1	• NIH workshop, Tracers • MS in Clinical Research – in progress • CTSA Un Meeting: Clinical Research in the COVID-era and Beyond • Will begin semester grant writing workshop 'Clinical Trials' sponsored by IFH • CLIC KL2-PI Directors Group Visitors Scholars Program: Duke University: 4/9/21

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS
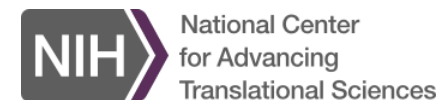
KL2 Scholars' Highlights (continued)

Scholar name	Publications # 1st /middle author/ submitted	Grants submitted/ future submission	Oral presentations	Other
Chintan Dave, PhD	9/1/2	R01, 6/20 PCORI, pending	2	• Rutgers Program for Early Career Excellence • Annual Gerontology Society of America
Elissa Kozlov, PhD **	2/1/2	R21, 12% K76, Beesen, score 31 K23, 2/20	2	• PCRC workshop • CTSA/IFH Dissemination and Implementation Intensive

*URM, **Female

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS

Career Development Activities/Opportunities

- Nicholas Ponzio, PhD, MS, presented "improv to Improve workshops" to current scholars on 5/27/20.
- Leveraged the e-Commercialization handbook (Academic Entrepreneurship) located on the CLIC website (https://clic-ctsa.org/education/academic-entrepreneurship-medical-and-health-scientists) - distributed to scholars
- Scholars informed of RBHS faculty development/mentoring events and various workshops and seminars including: BERD Workshops, RITMS Seminars, as well as others relevant to their career development

Advertising/Public Relations

- NJ ACTS/KL2 Website launched
- NJ ACTS/KL2 Newsletter distributed; Weekly/Bi-Weekly announcements, deadlines, reminders ongoing

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS

Leadership/Administrative Activities

- Conducted intensive reviews of current KL2 Scholars, convened the Executive Committee and reappointed current Scholars

- Badging (Workforce, KL2, TL1)

- Competency Training (Workforce, KL2, TL1)

- Outcome Metrics
  - Dr. Radovick is currently a member of CLIC's Careers Metric QI Committee

- Peer Learning - K scholars mentor T scholars in the planning stages

- Strategy for Diversity and Inclusivity
  - Working with the Medical School, Department Chairs and Graduate Programs to develop pipeline

Meetings

NJ ACTS External Advisory Board (EAB) Meeting – 4/30/2020

"Mini' EAB (Workforce, KL2, TL1) – 12/18/2020

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS
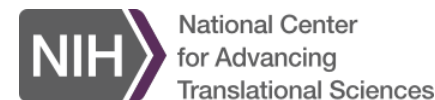
RFAs distributed – Opportunity to increase funding as well as number and diversity of scholars in program

- NOSI. NCCIH Admin Supplement
  Proposals Due: October 1, 2020
  11 inquiries received; did not meet eligibility criteria, however

- NIH Diversity and Re-entry Supplements
  Internal Submission: October 15, 2020
  NIH Deadline: November 1, 2020
  15 inquiries and 3 applications received
  2 candidates chosen to submit applications (2 RWJMS)

- KL2 – Second Year Cohort
  Applications Due – Nov 1, 2020
  Awardees to be Notified – Jan 15, 2021
  18 inquiries and 10 applications received (1 NJIT; 3 NJMS (1PU); 3 RWJMS; 1 SON; 1 SPH; 1 SOSW)

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS
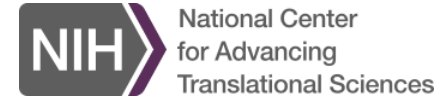
Society of Scholars

- Increased the membership in the Society of Scholars – currently 22 members (1 GSAPP; 1 IFH; 2 NJMS; 6 RWJMS; 1 SoN; 4 SoPharm; 4 SPH; 3 SoSW)

- "Meet and Greet" held on 9/22/20. 19 K Scholars presented; 6 T1 Fellows attended
    - Opportunity to foster collaborations among scholars - 3 collaborations initiated

Academy of Mentors

- Increased membership – additional faculty since last grant cycle include:
    - Christoph Buettner, MD, PhD - RWJMS
    - Lia Nower, PhD - SoSW
    - Bishr Omary, PhD - RWJMS
    - Hatem Sabaawy, MD, PhD - RWJMS/CINJ

New Jersey Alliance for Clinical and Translational Science

2020-2021
KL2 PROGRESS and PLANS
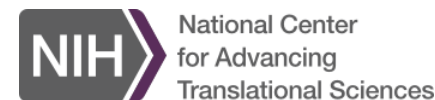
PLANS:

- 2nd Year Scholars Concluding Presentations – Late Winter 2021
  - Scholars discuss research achievements in a formal oral presentation (Mentoring Committee and EC)
- Organize Academy
  - Develop focus areas relevant to scholars for mentorship and collaboration
- Adopt recommendations from CLIC Careers Metric QI Committee
- Develop mentorship opportunities with TL1
- Develop Mentoring Contract
- Work with University to promote diversity
  - Pipeline development with clinical departments for physician-scientist career development
- Promote mentoring programs (RBHS)
- Pipeline development with clinical departments for physician-scientist career development

New Jersey Alliance for Clinical and Translational Science
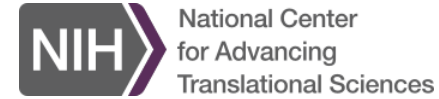
2020 NJ ACTS Retreat Informatics Core – Career Development
November 13, 2020

9:00 am - 3:00 pm

New Jersey Alliance for Clinical and Translational Science

Informatics Core Leads and Co-leads

Frank Sonnenberg, MD
Professor of Medicine, RWJMS
CMIO RWJBH-Rutgers Health Medical Group

David J. Foran, PhD
Professor of Pathology, RWJMS
CIO & Exec. Dir., Comp. Imaging & Biomedical Informatics
Rutgers Cancer Institute of New Jersey

Barr von Oehsen, PhD
Associate Vice president
Rutgers Office of Advanced Research Computing

Stephen Crystal, PhD
Distinguished Research Professor
Director, Center for Health Services Research
Rutgers Institute for Health (IFH)

Yi Chen, PhD
Leir Chair & Professor of Business Data Science
New Jersey Institute of Technology

New Jersey Alliance for Clinical and Translational Science

Planned Informatics Training Programs

- Phased approach
- Expand existing informatics electives into fellowship opportunities.
- Badging program to enable formal recognition of skills in focused areas of informatics methodologies.
- Leveraging course offerings in the School of Health Professions
- Longer-term: full fellowships in clinical and bioinformatics with a focus on clinical service, supporting research and informatics research.
- Mentoring from NJ-ACTS partners in informatics methodologies

Skills acquired and mentored by collaborating institutions and cores:

- Machine-learning
- Natural Language Processing
- Social media analysis
- Management of large claims databases
- Merging of claims data with clinical (EHR) data.
- Database management and data analysis
- Bioinformatics – genomics, proteomics, phenotyping from clinical data
- Data extraction from EHR's
- Optimization of EHR's to support research.

Outreach Medical Education and Training Programs for Botswana

Google Cloud Platform
Dynamic Quiz Banks
Near Real-Time Digital Telepathology

In September 2019, a team from Rutgers including Drs. Foran, Mayer, Marlink visited w/ local cytopathologists, cytotechnologists, and pathology residents at University of Botswana and the National Public Health Lab. While there we had the opportunity to visit hospitals within the Botswana healthcare system while observing current workflows, resources and staffing. Based on subsequent discussions with our colleagues at Botswana and Rutgers, the overarching goals of the proposed work focuses on four well-defined projects: **(1) Implementation and adoption of low-cost, high-fidelity digital pathology technology; (2) Design, development and deployment of point-of-contact computer-assisted diagnostic tools; (3) Deployment of Google cloud-based dynamic, database of "gold-standard" consensus graded cases to query against to provide asynchronous, clinical decision support and training to pathologists and technicians in Botswana; (4) Expansion of Botswana Cancer Module for existing EHR .**

Outreach Medical Education and Training Programs for Botswana

Dynamic Quiz Bank: A dynamic pathology quiz bank that features "live" virtual telemicroscopy, automatic scoring and a growing database of oncology cases is already being developed at Rutgers Cancer Institute of NJ in collaboration with the Rutgers Global Health Institute for training both locally and at a distance.
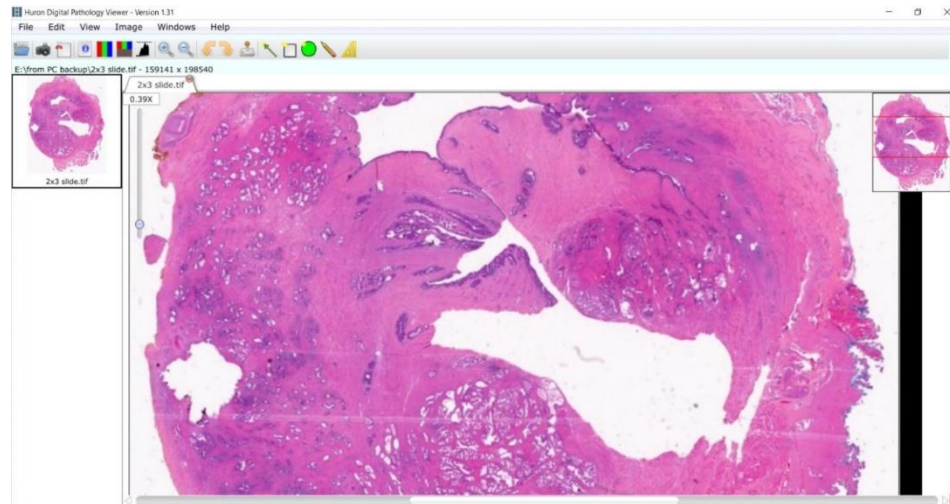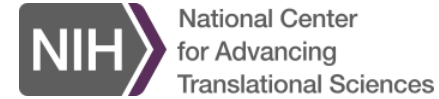
Collaboration and Multi-Disciplinary Team Science
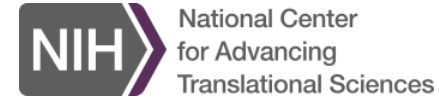
Leads and Co-leads

Edmund C. Lattime, Ph.D.:   Professor of Surgery, Rutgers Robert Wood Johnson Medical School
Associate Director for Research and Education Affairs
Rutgers Cancer Institute of New Jersey

Biju Parekkadan, Ph.D.:   Associate Professor Biomedical Engineering, Rutgers University
Associate Professor of Medicine,
Rutgers Robert Wood Johnson Medical School

Nancy E. Reichman, Ph.D.:   Professor of Pediatrics, Rutgers Robert Wood Johnson Medical School
Visiting Professor of Economics, Princeton University

New Jersey Alliance for Clinical and Translational Science

Team Science Progress to Date

Team Science Symposium
Jan. 28, 2020
"Academic Careers in the Era of Team Science"

- **Panel 1: Examples of the importance of team science**
  - Shawna Hudson, PhD, Rutgers Family Medicine and Community Health
    - *How Do You Develop and Sustain Team Based Research? My Research Experiences in Cancer Survivorship Care*
  - Edmund Lattime, PhD, Rutgers Cancer Institute
    - *Team-based Translational Immunology/Immunotherapy Studies for the Development of Effective Cancer Therapeutics*
  - Sam Wang, PhD, Dept of Molecular Biology and Princeton Neuroscience Inst.
    - *Team-based Basic Neuroscience: Brain-Wide Approaches To Working Memory, Learning, and Autism*

Presentations on NJ ACTS website
TL1/KL2 awardees attended as part of their curriculum

New Jersey Alliance for Clinical and Translational Science

Team Science Progress to Date
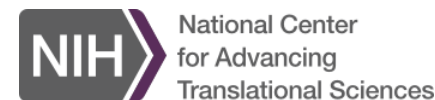
Team Science Symposium
Jan. 28, 2020
"Academic Careers in the Era of Team Science"

- **Panel 2: Academic promotion and tenure in the era of team science**
  - Holly J. Falk-Krzesinski, PhD, Northwestern University and Elsevier
    - *How Expanding Recognition and Reward in the 21st Century: A Focus on Promotion and Tenure Policy for Team Science*
  - Julie Thompson Klein, PhD, Wayne State University and Transdisciplinarity Lab, ETH-Zurich
    - *Scoping Recognition and Reward for Collaboration: Inter/National Perspectives*
  - Susan McHale, PhD, Pennsylvania State University
    - *P&T Policies on Team Science in CTSA Colleges of Medicine: Best Practice or Mixed Message?*

Presentations on NJ ACTS website

TL1/KL2 awardees attended as part of their curriculum

New Jersey Alliance for Clinical and Translational Science

Team Science Progress to Date

Powerful Collaboration Tool Launched in Year 1
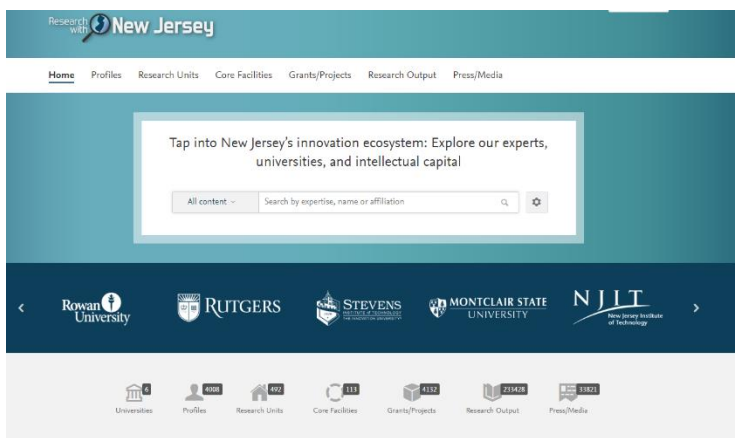
- Online gateway that lets New Jersey's academics, companies, and entrepreneurs identify experts, facilities, publications, intellectual property, news, and events in five of the state's universities: Princeton University, Rutgers University, New Jersey Institute of Technology, Stevens Institute of Technology, and Rowan University.

- Supported by six of New Jersey's leading business and industry organizations: the New Jersey Business & Industry Association, Choose NJ, Bio NJ, the HealthCare Institute of New Jersey, the Research and Development Council of New Jersey, and the New Jersey Tech Council.

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

*Launch of new Team Science Course
Coordinating with TL1 and KL2 Programs*
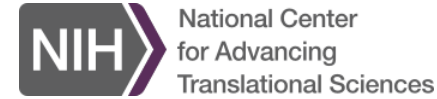
- Course Directors: Biju Parekkadan, Raffaele Gigliotti

- Spring 2021 course for all K and T awardees in the CTSA

- Description: This course provides an introduction to the theory and practice of team science and explores the practical and theoretical knowledge and skills necessary to lead and participate in successful interdisciplinary research teams across a variety of biomedical disciplines. As a result of participating in the course, students will understand the barriers, approaches, benefits, limitations, and strategies associated with interdisciplinarity; identify the specific competencies necessary for cultivating effective research collaborations; and recognize the skills required in adapting to multiple contexts, roles, and organizational responsibilities as a team member and team leader.

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

Developing Team Science Experiential Seminar Series

- Will build on the January 2020 symposium on academic careers in the era of team science

- Speakers will be recruited from NJ ACTS institutions and programs

- Description: This seminar series will showcase requirements for successful team science projects spanning the translational continuum and featuring projects from Basic Science, Population Science, and Clinical Trials

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

Team Science Internships (Oct.—Dec. 2020)
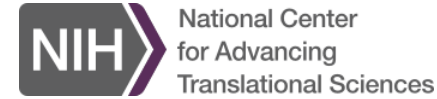
- Collaboration with *Workforce Development* Core
  - Hosen Arman
    - Senior undergraduate bio major at RU Camden
  - Ziyad Razeq
    - RU grad and currently in RU Master of Science in Biomedical Sciences program
- Activities
  - Writing scholarly publications
  - Developing and implementing survey for NJ ACTS pilot grant recipients
  - Taking inventory of team science projects across the consortium

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

Team Science Internships (Oct.—Dec. 2020)
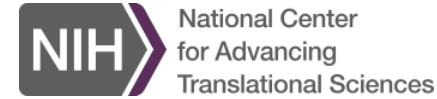
Scholarly papers on "top-down" approach to fostering team science

- Case studies on evolution, implementation, future directions of RU initiatives
- Submitting in February to Special Focus issue in *Journal of Clinical and Translational Science* on Team Science Interventions

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

Team Science Internships (Oct.—Dec. 2020)
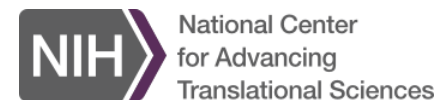
Survey for NJ ACTS pilot grantees and other collaborative Team Programs such as REACH

- *Please evaluate the collaboration within your team*

	Very Poor	Poor	Fair	Good	Excellent
a. Communication among collaborators.	•	•	•	•	•
b. Ability to capitalize on the strengths of different researchers.	•	•	•	•	•
c. Resolution of conflicts among collaborators.	•	•	•	•	•
d. Productivity of collaboration meetings.	•	•	•	•	•
e. Overall productivity of collaboration.	•	•	•	•	•

New Jersey Alliance for Clinical and Translational Science

Team Science In Process

Team Science Internships (Oct.—Dec. 2020)
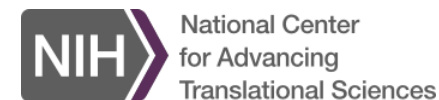
NIH MPI projects across consortium as models of Team Science

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Core Interactions: Collaborations and Activities

	Informatics	Community	Team Science	Workfroce	Pilots	BERD	Regulatory	Special Pops	PCI/LTIC/LRIC	Biomarkers	Machine Learning	TL1	KL2
Informatics													
Community													
Team Science													
Workdorce			Internship										
Pilots			Using pilot data as models of Team Science										
BERD													
Regulatory													
Special Pops													
PCI/LTIC/LRIC													
Biomarkers													
Machine Learning													
TL1			Team Science Course and seminar series										
KL2			Team Science Course and seminar series										

Thank you!

The NJ ACTS Biomarker Core

Marila Gennaro, MD, MSc

NJ ACTS Retreat

November 13, 2020

Biomarker Core Lead & Rutgers Collaborators

Marila Gennaro, MD MSc
Professor Medicine
Rutgers NJ Medical
School

Collaborators:
Natalie Bruiners
Pratik Datta
Valentina Guerrini
Deb Handler
Abhilasha Mishra
Pankaj Mishra
Alberta Onyuka
Rahul Ukey

David Alland
Marty Blaser
Pat Bocarsly
Mary Carayannopoulos
Jeff Carson
Cecile Feldman
Dan Fine
Sunanda Gaur
Judith Graber
Shuang Guo
Perry Halkitis
Sabiha Hussain
Sugeet Jagpal
Larry Kleinman
Alfred Lardizabal

Ned Lattime
Steve Libutti
Peter Lobel
Bishr Omary
Rey Panettieri
Renata Pasqualini
Abe Pinter
Claire Philipp
Maressa Pollen
Jared Radbel
Sally Radovick
Henry Raymond
David Sleat
Josh Vieth

Core Supported Projects
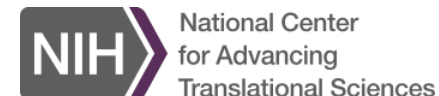
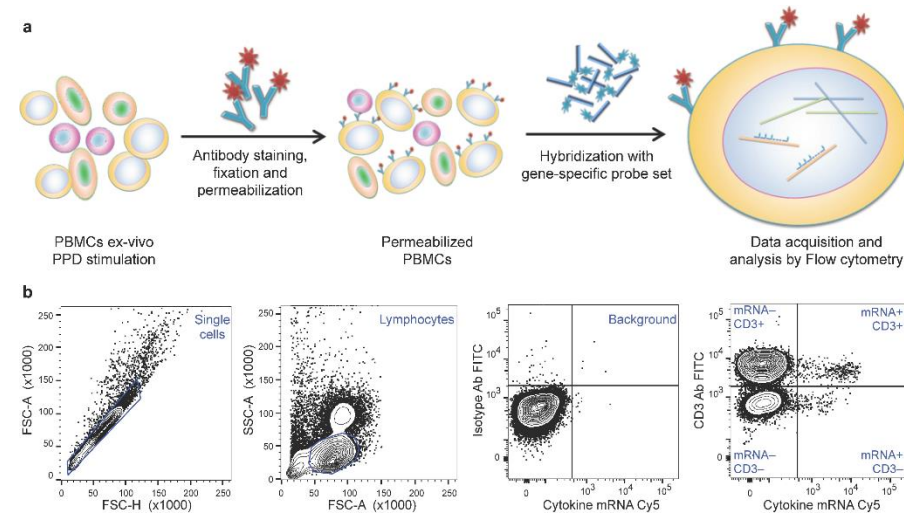| Project Title	Brief Description
miRNAs as biomarkers of asthma exacerbation	Investigate circulating microRNA as non-invasive biomarkers of asthma exacerbation
Clinical trial (VIDAS-TB, Biomerieux)	A whole-blood-based, fully automated platform for diagnosis of *M. tuberculosis* infection (multiple clinical trial phases)
Rutgers Corona Cohort (RCC)	Seroprevalence of SARS-CoV-2 over time in a longitudinal cohort of Rutgers health care workers established at the pandemic onset
SARS-CoV-2-specific humoral and cellular immune responses	Detection of SARS-CoV-2 specific antibodies, neutralizing titer and virus-specific T and B cell responses in convalescent donors among Rutgers employees
Seroprevalence of SARS-CoV-2 in Essex county, NJ	Venue-based approach to study seroprevalence of SARS-CoV-2 using a blood microsampling device
Seroprevalence of SARS-CoV-2 in volunteer firefighters	Seroprevalence of SARS-CoV-2 among firefighters recruited for the NJ Firefighter Cancer Assessment and Prevention Study
Convalescent plasma therapy for COVID-19	To correlate the clinical outcome of convalescent plasma treatment of COVID-19 with the properties of the donor plasma
Severe SARS-CoV-2 induced illness in children	To identify abnormal immune phenotypes in children diagnosed with pediatric multisystem inflammatory syndrome or severe acute COVID-19 illness
SARS-CoV-2 prevalence in dental health care workers	To determine the prevalence of SARS-CoV-2 specific antibodies in dental health care workers
SARS-CoV-2 seroprevalence in people with HIV	Detection of anti-SARS-CoV-2 antibody using mail in finger prick microsampling device
Seroprevalence of SARS-CoV-2 in Hispanic/Latinx communities	Investigate association between race/ethnicity and SARS-CoV-2 prevalence
Seroprevalence of SARS-CoV-2 in dental patients	Detection of SARS-CoV-2 specific antibodies in dental patients recruited at Rutgers School of Dental Medicine's dental clinics
Post COVID care program	Detection of SARS-CoV-2 specific antibodies in patients recruited from Saint Barnabas Medical center and studying long-term effects of COVID-19 infection

Fluorescence in situ hybridization flow cytometry (FISH Flow)

An RNA flow cytometry platform that is suitable for **disease staging and assessment of disease reactivation/exacerbation risk** because it can yield dynamic read-outs.

Please refer to our *Nature Protocols* and other publications:
https://experiments.springernature.com/articles/10.1038/nprot.2017.039
https://www.frontiersin.org/articles/10.3389/fimmu.2018.02127/full
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0144904
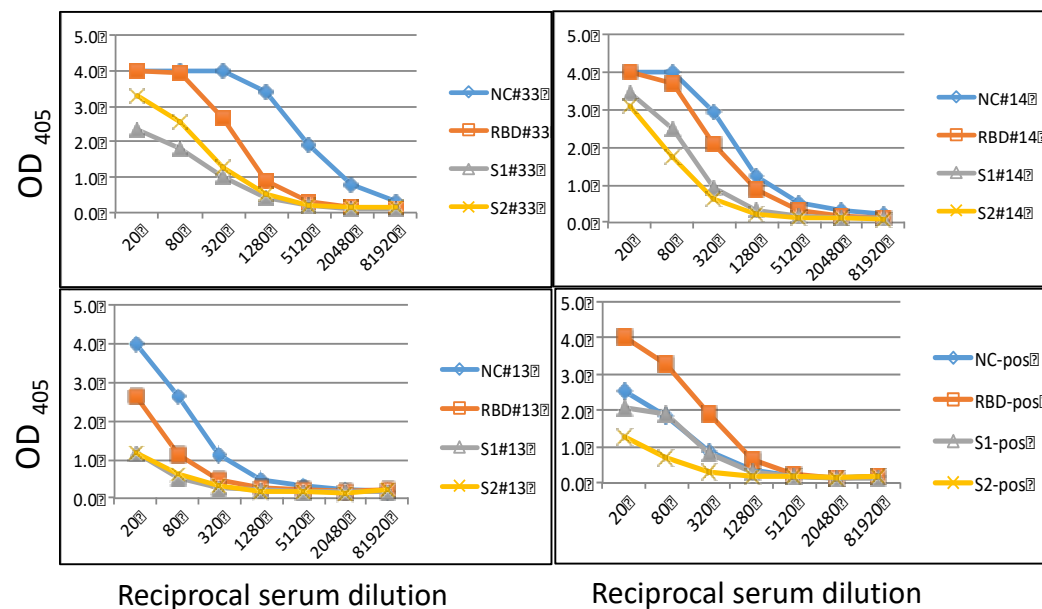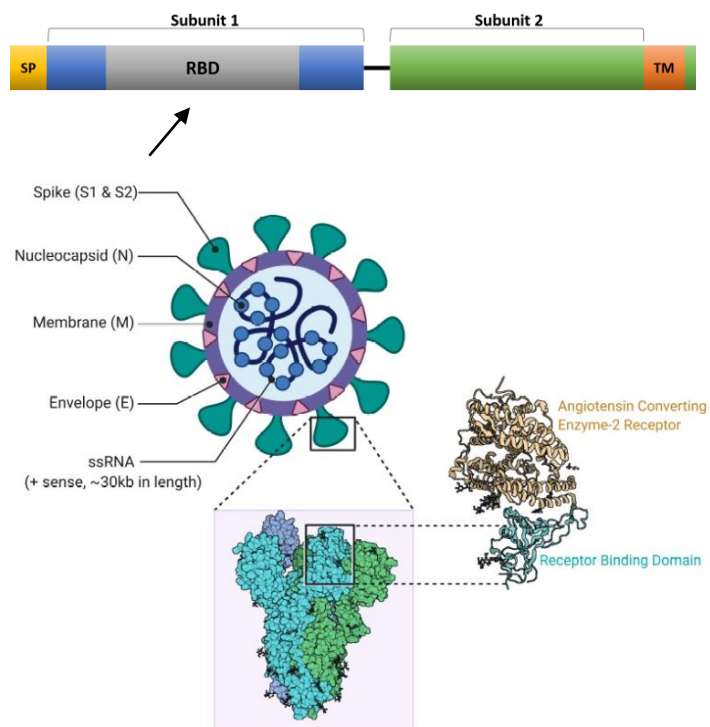
COVID-19 ELISA

Antigens: S1 S1 RBD S2 N

(Collaborator: Pinter)

The Rutgers COVID-19 ELISA lab

COVID-19 ELISA

Since the beginning of the COVID-19 pandemic, our automated **ELISA laboratory has tested >5,000 sera** and run over 650 96-well plates.

TMB substrate

colored product

Enzymatic color reaction proportional to antibody

secondary antibody to Igs

sera or plasma

specific viral antgens

National Center for Advancing Translational Sciences

Antibody effector functions

a) **Virus neutralization.** To quantify neutralizing antibody titers to SARS-CoV-2 utilizing VeroE6 and Hela-ACE2.

b) **Antibody-dependent enhancement (ADE)** and **FcγR-mediated virus uptake**. To determine involvement of FcγR in viral uptake by using engineered B cells that express no FcγR or each FcγR class.
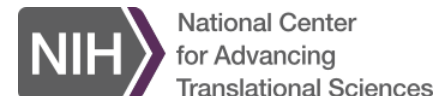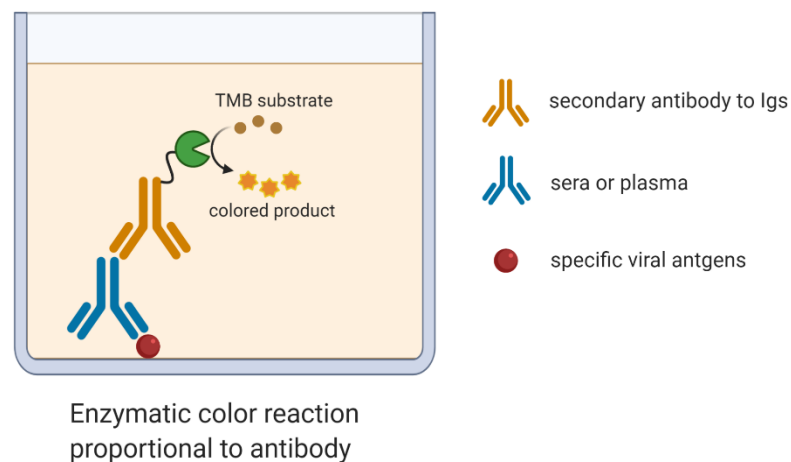
c) **Endocytosis/Phagocytosis**. To investigate uptake of antigen-coated fluorescent beads pre-incubated with SARS-CoV-2 donor plasma or with uninfected plasma.

d) **Antibody-mediated cytotoxicity (ADCC)**. To investigate the immune mechanism through which Fc receptor-bearing Jurkat cells that naturally express a functional NFAT (nuclear factor of activated T cells) transcription factor that can recognize and kill antibody-coated target cells expressing viral-derived antigens on their surface.

e) **Complement-dependent cytotoxicity (CDC).** To determine whether antibody-coated target cells recruit and activate components of the complement cascade leading to the formation of a Membrane Attack Complex (MAC) on the cell surface and subsequent cell lysis of target Daudi cells**.**
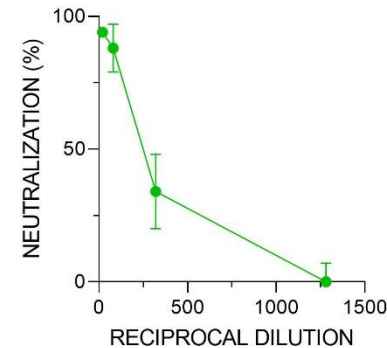
Neutralization assay. Plasma from a COVID-19 patient inhibiting infection of VeroE6 cells by SARS-CoV-2 .
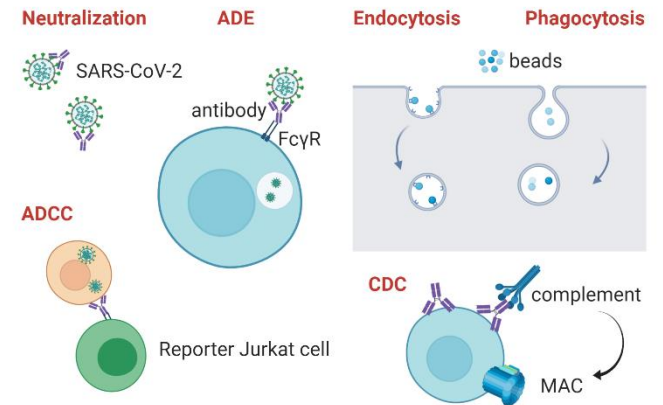
Schematic representation of antibody effector functions

Immunophenotyping of memory B cells and plasmablasts

B cells : CD19$^+$,CD20$^+$,CD14$^-$,CD16$^-$,CD3$^-$,CD4$^-$
PB- Plasma blast: CD19$^+$,IgD$^-$,CD38$^+$
NPB- Non plasma blast : CD19$^+$,CD38$^-$
DNM- Double negative Memory B cells: CD19$^+$,CD27$^-$,IgD$^-$
UM- Unswitched Memory B cell : CD19$^+$,CD27$^+$,IgD$^+$
SM- Switched Memory B cell : CD19$^+$,CD27$^+$,IgD$^-$
IgG$^+$SM - IgG$^+$ switched memory B cell : CD19$^+$,CD27$^+$,IgD$^-$,IgG$^+$
IgG$^-$SM – IgG$^-$ switched memory B cell : CD19$^+$,CD27$^+$,IgD$^-$,IgG$^-$
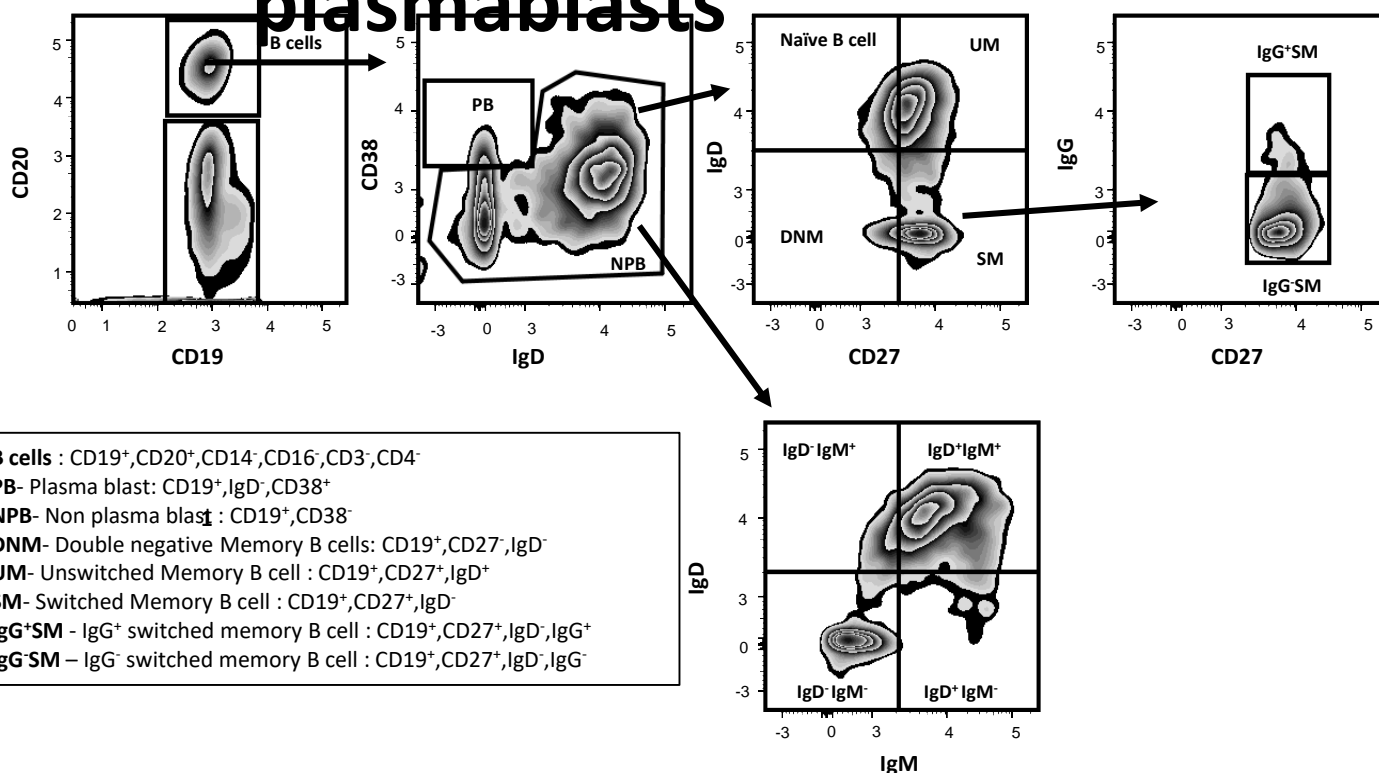
Accomplishments
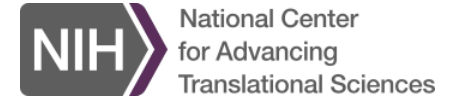
- **Collaboration with BERD** among NJ ACTS cores

- **Collaborations with investigators at other CTSA hubs**:
  - Tufts U, Johns Hopkins U, U Pittsburgh, U Texas, Galveston, Weill Cornell U

- **Grants**:
  - HL149450-S1 $483,420 (Direct); Pfizer, Inc. 61618273; various intramural grants; participation in U01AI122285-S1 (RCC study)
  - Four NIH grant submissions pending review

- **Publications**:
  - Guerrini V. et al. Lancet Respir. Med. (2020)
  - Radbel J. et al. J. Mol. Diagn. (2020)
  - Barrett E.S. et al. BMC Infect. Dis. (2020)
  - Bruiners N. et al. J. Lipid Res. (2020)
  - Barrett E.S. et al. Open Forum Infect Dis (2020)

Core services
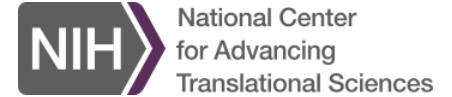
- **Consultation**, experiment planning, and service outsourcing
- **Assistance** with data generation for manuscript or grant preparation
- Set up projects as **collaboration**
- IgG, IgM and IgA antibody testing and titer determination
- Detection of IgG_1, IgG_2, IgG_3 and IgG_4
- Antibody effector functions
- Memory B cell and T cell immunophenotyping
- RNA flow cytometry

Future plans
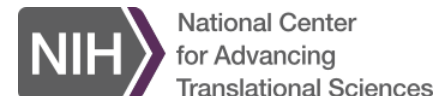
- **Establish a website** that informs the Rutgers audience on the type of consultations and services that the biomarker core can provide.

- **Continue and expand COVID-19-related services**.

- **Support studies on additional infectious and non-infectious diseases.**

- **Grow interactions with other NJ ACTS cores**, with particular emphasis on multidimensional data analysis.

A core of one
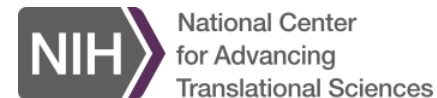
Natalie Bruiners, PhD

Pratik Datta, PhD
Pankaj Mishra, PhD
Rahul Ukey, PhD

Machine learning core

Leads / co-leads

Jonathan Cohen

Robert Bendheim and Lynn Bendheim Thoman Professor; Director

Princeton Neuroscience Institute

Nathaniel Daw

Huo Professor in Computational and Theoretical Neuroscience

Princeton Neuroscience Institute

Yael Niv

Professor

Princeton Neuroscience Institute

Innovation

Motivating scientific problem: taxonomic problems in mental illness hampering basic science (& individualized diagnosis / treatment etc).

Attack via data mining on patient records (PHQ-9 + chronic disease state, with Informatics) and via laboratory studies of cognitive neuroscience mechanisms in patients (with CCNP)

Today: two more foundational / infrastructural problems
- solutions hopefully applicable across areas

1. online data collection

Due to COVID (but also more generally) we need to measure behaviors of interest (decision making, learning) online via web browser

1. selecting appropriate tasks, implementing & tuning (plus server and recruitment infrastructure)

2. validation (e.g. test/retest, noise/power)

3. understand variation / dimensionality / overlap

More broadly applicable (e.g. Core Neuropsychological Measures for Obesity and Diabetes project)
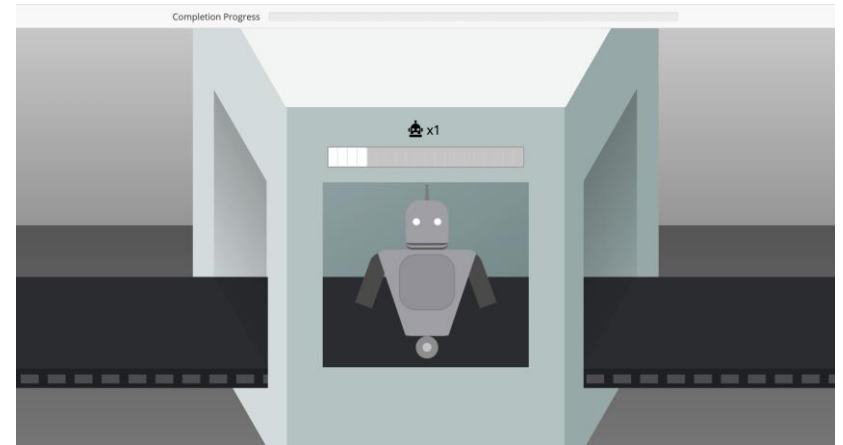
2. validation / estimation

Low-effort subjects, bots
- multi-pronged effort to fight
- surprising results showing ignoring this can proudce spurious effects

Estimating behavioral parameters, and their distributions, across test/retest surprisingly tricky
- recent reports of atrocious performance, down to poor estimation
- hierarchical estimation software (respect complex structure of repeated measures, groups, etc.)

3. dimensionality reduction & clustering

problem: many symptom reports (or other labs), and/or many behavioral parameters
- what are the underlying dimensions or clusters
- tricky due to non-Gaussian measurement, discrete or continuous variation

general framework using variational autoencoders
- fast, robust, scaleable

applicable to many problems (e.g. genomics, proteomics?)

Service

Releasing code for several data analysis problems

1. validated learning / decision task battery for online data collection
2. approx. expectation maximization for fast hierarchical model estimation
3. variational autoencoders for scalable, nonlinear factor analysis

Pursuing a collaboration rather than service center model

several projects started (mainly in psychiatry, and relationship to other clinical illness) but seeking seeds for others

also have actual service center (CCNP) for psychiatric patient studies, exploring juiced up data analytics services here

Mentoring

Starting out with one TL-1 trainee (Miles)

general question how best to provide training here (workshops? classes?)

Intra-NJ ACTS Collaborations

- TL1 Program: Mentee Miles is a TL1 recipient

- Informatics: PHQ9 study (also Miles study)

- Special populations: Crystal / OUD

Plans

- Innovation: build out infrastructure; conduct actual studies
- Service: Distribute code; pursue additional collaborations; add data analysis within CCNP; explore training opportunities

Core Interactions: Collaborations and Activities

	Informatics	Community	Team Science	Workfroce	Pilots	BERD	Regulatory	Special Pops	PCI/LTIC/LRIC	Biomarkers	Machine Learning	TL1	KL2
Informatics											PHQ9		
Community													
Team Science													
Workdorce													
Pilots													
BERD													
Regulatory													
Special Pops											Crystal / OUD		
PCI/LTIC/LRIC													
Biomarkers													
Machine Learning													
TL1											Miles mentoring		
KL2													

Clinical Trials Office (CTO) Trial Innovation Network (TIN) Activities

Mark Einstein, MD (NJMS)

Sunanda Gaur, MD (RWJ)

Howard Kipen, MD (EOHSI)
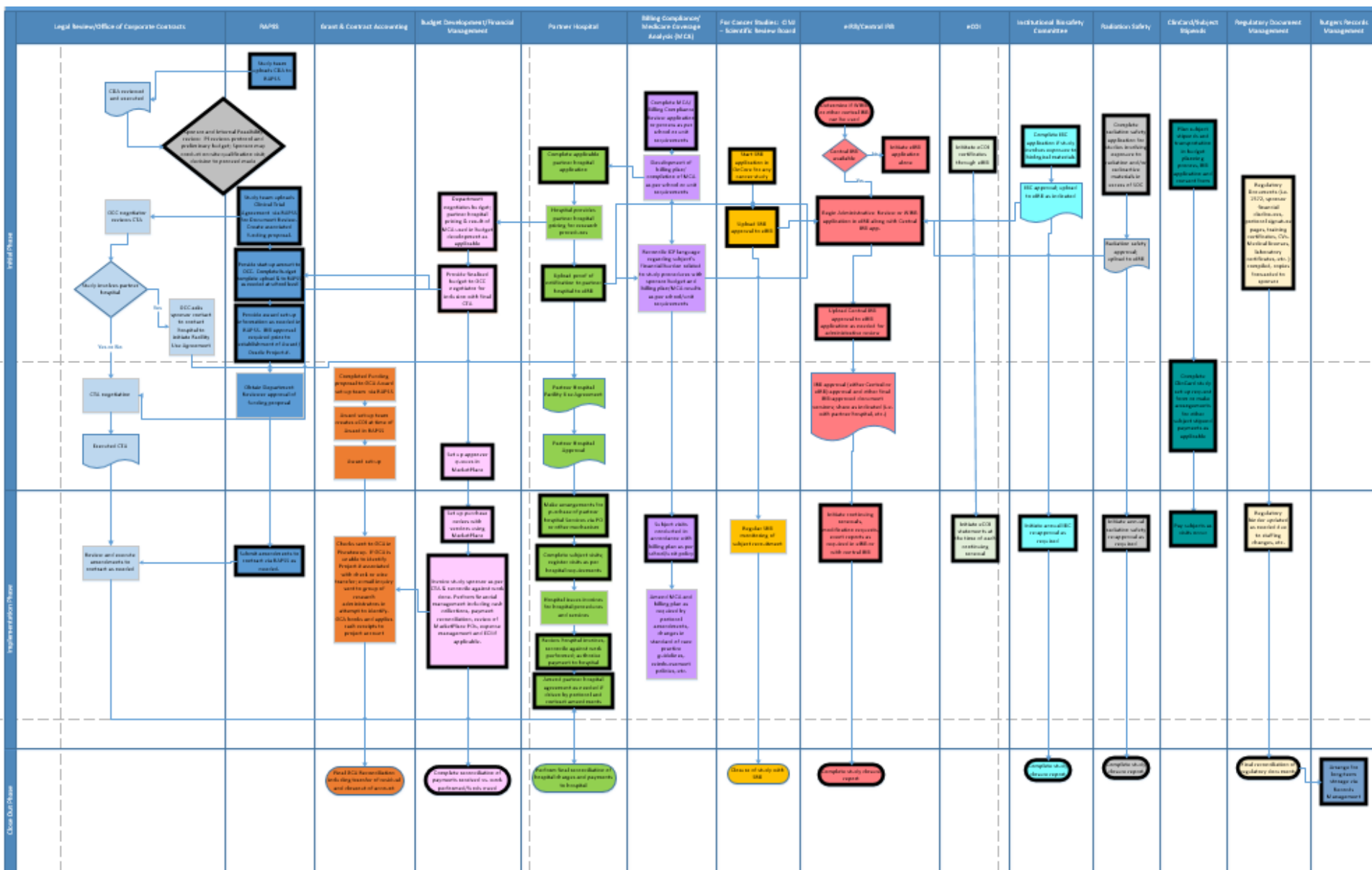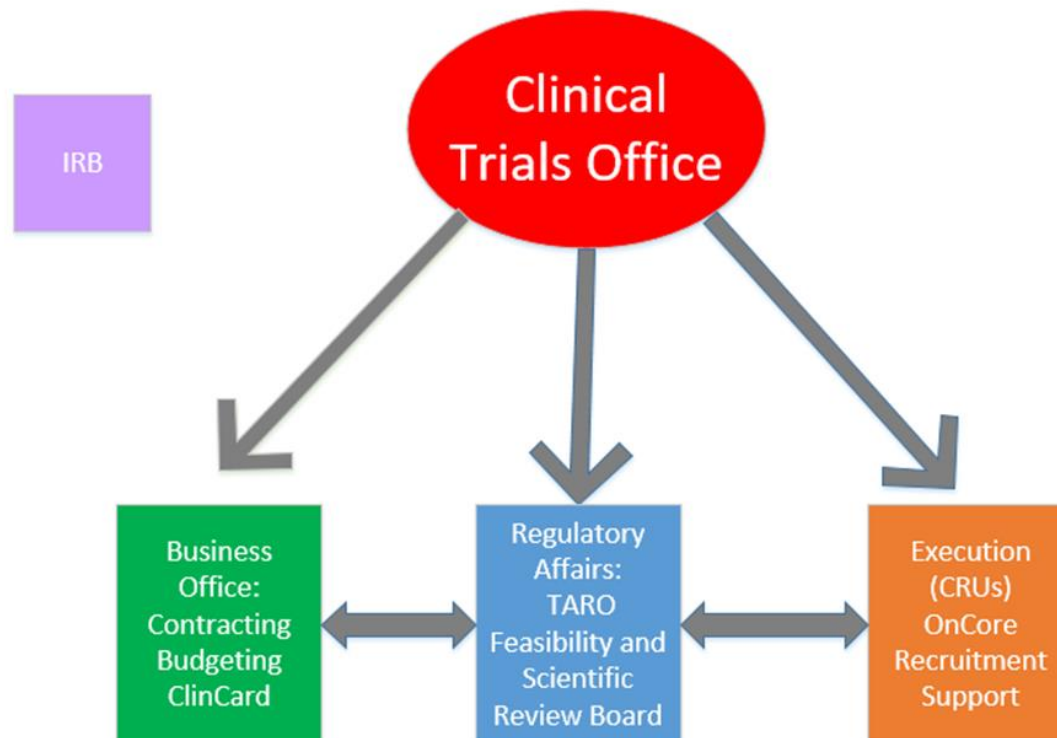
Nancy Reilly, RN, MS (NJ ACTS)

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Current RU Workflow for an industry-funded trial

Organizational Structure of Proposed RBHS Clinical Trial Office

Mission of the RBHS Clinical Trials Office

- Improve **efficiency** of start-up processes
- Improve the quality of clinical trials conducted at RBHS & assure that studies consistently meet **recruitment** targets
- Assure compliance with applicable regulations (specifically with regard to **clinical research billing**)
- **Standardize** clinical research policies and procedures across RBHS

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Scope of new RBHS Clinical Trials Office

- Clinical Research studies conducted by an **RBHS** principal investigator (at a domestic location) with **billable clinical procedures**, irrespective of funding source

- Does not apply to studies conducted by faculty members whose primary academic appointment is with CINJ

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Technology Solutions to be housed within the CTO

- OnCore Clinical Trial Management System

- Deep 6 AI Cohort Builder

- Greenphire's ClinCard

How will we improve the efficiency of study start-up processes?

- Centralize, under one virtual roof:
    - Contracting (started early May, 2020)
    - Budgeting
    - Medicare Coverage Analysis (MCA)
    - Partner hospital application process

- OnCore will be a central "source of truth" for applicable studies & the means of communication between all involved parties

COVID Studies at NJ ACTS sites

- Moderna and J&J COVID vaccine trials (NJMS, RWJ, EOHSI)
- EOHSI with multiple studies for prevention of air transfer of COVID
- COVID tests validated- Cepheid, low cost tests for LMICs (NJMS)
- COVID HCW study (RWJ, NJMS)

Intra NJ ACTS Activity

- Regulatory
  - Formation and co-management of the Scientific Review Board (SRB)
- BERD
  - Data Management for COVID studies
- Workforce Development
  - Clinical Research Fellow at RWJMS CRU
  - Initiation of ACRP e-Learning system (over 40 individuals have accessed to date)
- KL2 Scholar Assistance

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CTSA Network Activity

Likely to Start:

- Vestibular ER Consults vs Imaging (Hopkins Primary site)

- ACTIV2: Adoptive Platform for COVID Outpatient management (NIAID)

- Head and Neck recurrence remission using cannabinoid derivatives (Arkansas)

Considering:

- ABC Science Collaborative (Duke)

- Sphincterectomy for Acute Pancreatitis, SHARP trial (MUSC)

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CTSA Network Activity

PAR-19-099 Clinical and Translational Science Award (CTSA) Program: Collaborative Innovation Award (U01 Clinical Trial Optional) https://grants.nih.gov/grants/guide/pa-files/par-19-099.html

- Mother/Child Dyad Microbiome (Panettieri, Blaser RU PIs)
  - UNC
  - UIC
  - Rutgers

- **WELLMAMA-CTSA Maternal Health Research Resource Action Hub (WELLMAMA Action Hub) (Einstein RU PI, Campbell)**
  - Northwestern
  - UAB
  - Rutgers

CTO and TIN Key Personnel

CRU Leads:

- Sunanda Gaur, MD
- Howard Kipen, MD
- Mark Einstein, MD
- Narayanan Ramasubbu, DMD
- Nancy Reilly, RN, MS- Lead CTO

NJMS:

- Randall Teeter, MS (NJMS CRU Lead)

CTO Personnel

- Elise Lewis, Contracts Manager
- Jonathan Carter, IT Business Systems Analyst
- Justin Blucher, Recruitment Specialist
- Alexandra Young, Feasibility Navigator

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