



ANNUAL REPORT

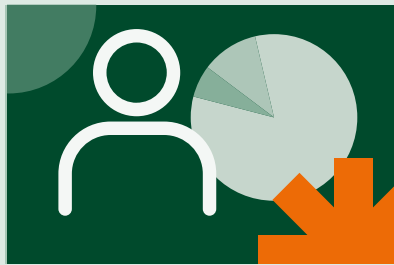
FISCAL YEAR 2021

UNIVERSITY
OF MIAMI

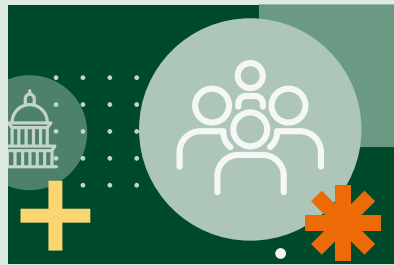


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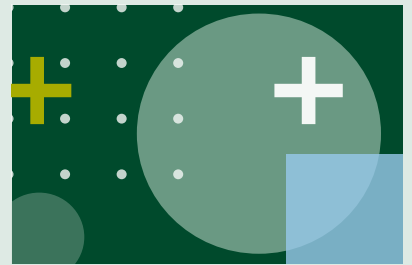
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WELCOME TO THE MIAMI CTSI FY21 ANNUAL REPORT

The FY21 Annual Report showcases the accomplishments of the Miami CTSI in clinical and translational research, education, and community outreach over the course of the fiscal year.

NOTE FROM THE DIRECTOR:

This Annual Report presents the tireless work being undertaken by the teams of people keeping the CTSI moving forward under historically challenging circumstances. Each infographic and story highlights our successful shift to new ways of thinking, working, interacting, and collaborating. I am proud of the innovative work we are doing and greatly appreciate the teamwork of the outstanding staff, program directors and countless members of our CTSI team. I am looking forward to our next year of accomplishments.



A handwritten signature in blue ink that reads "Ralph L. Sacco". The signature is stylized and cursive.

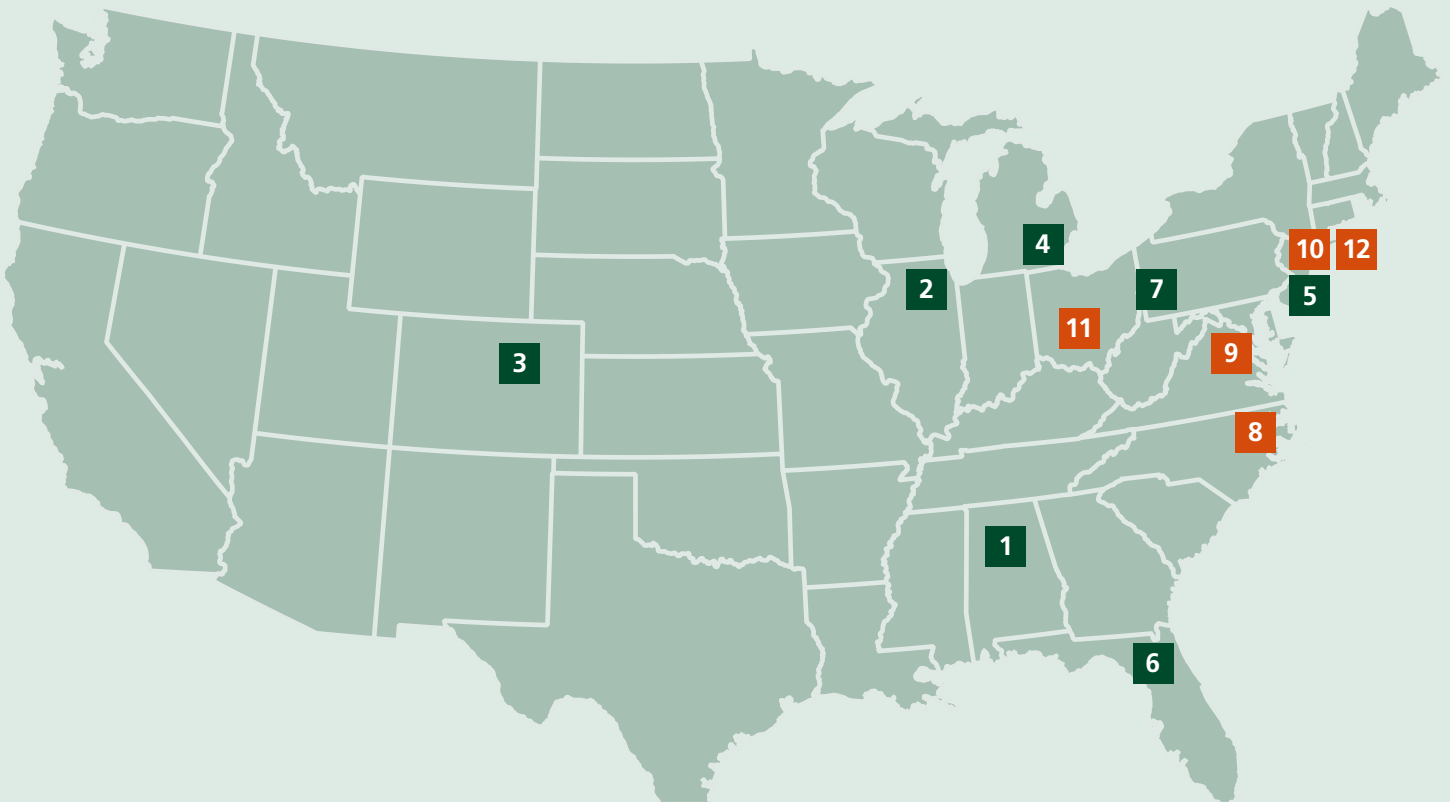
Ralph L. Sacco, MD MS



MISSION STATEMENT

The mission of the Miami Clinical and Translational Science Institute (CTSI) is to be indispensable as the scientific home for clinical and translational (C/T) research, transforming University research infrastructure to advance excellence in culturalized C/T research.

CTSA FY21 COLLABORATIONS:



1 UNIVERSITY OF ALABAMA BIRMINGHAM
Continuing partnership on the I-Corps@NCATS supplement to expand the program

2 UNIVERSITY OF ILLINOIS AT CHICAGO
Adopting and expanding the CIRTification training program in human research protections that is tailored to the unique roles of community research partners

3 UNIVERSITY OF COLORADO
Implementing a Research Mentoring Training Program for junior faculty as part of mentor-mentee teams with their mentors

4 UNIVERSITY OF MICHIGAN ANN ARBOR
Implementing the UMiamiHealthResearch.org portal, lay-friendly health research site to improve community participant recruitment, including healthy participants, into clinical trials

5 NEW YORK UNIVERSITY LANGONE; ALBERT EINSTEIN SCHOOL OF MEDICINE
CONTAIN COVID-19 convalescent plasma clinical trial

6 UNIVERSITY OF FLORIDA
OneFlorida Clinical Research Consortium; Network Science collaborations

7 UNIVERSITY OF PITTSBURGH
Participating in the Accrual to Clinical Trials (ACT) Network for sharing of clinical data

TIN TRIALS

- 8 DUKE**
- 9 JOHN HOPKINS (3 TRIALS)**
- 10 NYU LANGONE**
- 11 OHIO STATE**
- 12 COLUMBIA**


CTSI AWARDS

FY21 MENTORED TRANSLATIONAL RESEARCH KL2 AND INSTITUTIONAL SCHOLAR AWARDS

The award provides a structured research training environment that allows early stage faculty to acquire the skills and experience needed to become outstanding independent clinical and translational investigators. Awardees will receive mentorship, an individualized research and career development plan, experiential training with established faculty, and access to educational programs and supportive resources through CTSI's various programs.

The Miami CTSI named four new scholars for FY 2021. They include three NCATS-funded KL2 scholars and one institutional scholar jointly funded by the CTSI and the College of Arts and Sciences.

NEW FY21 SCHOLARS:




Merline Benny, MD*
Assistant Professor,
Pediatrics, NCATS KL2 Scholar

Protective role of CXCR7 in neonatal hyperoxia induced systemic vascular dysfunction in adulthood




Marissa DeFreitas, MD
Assistant Professor,
Pediatrics, NCATS KL2 Scholar

Soluble klotho as a predictor of reduced nephron endowment and kidney injury in preterm infants



Yelena Drexler, MD
Assistant Professor,
Medicine, NCATS KL2 Scholar


Apolipoprotein M and S1P as Novel Biomarkers of Glomerular Lipotoxicity in Nephrotic Syndrome



Katlyn Meier, PhD
Assistant Professor,
Chemistry, CTSI Institutional Scholar


Metal-centric approach to medicine: Combining spectroscopy, in vivo imaging, and quantum-chemical calculations to define metal-protein interactions in the progression and treatment of neurodegenerative disease

ACTIVE SCHOLARS FROM FY20:



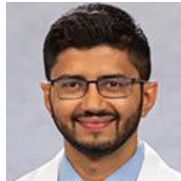
Corrina Levine, MD, MPH
Assistant Professor,
Otolaryngology, NCATS KL2 Scholar

Using an Integrated Profile of Chronic Rhinosinusitis to Customize Care and Mitigate Disparities



Ayham Alkhachroum, MD
Assistant Professor,
Neurology, CTSI Institutional Scholar

Electrophysiologic Biomarkers of Consciousness Recovery after Traumatic Brain Injury: The EBC Recovery Study



Jashodeep Datta, MD
Assistant Professor,
Surgery, CTSI Institutional Scholar

Overcoming tumor-intrinsic mechanisms of immune exclusion defined by Ras-p53 cooperative signaling in pancreatic adenocarcinoma

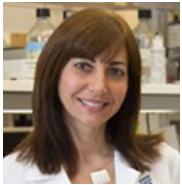
* Dr. Benny was awarded an NIH K08 in August 2021 and ended her KL2 award.

CTSI AWARDS

FY21 PILOT AWARDS

CTSI awarded five new Pilot Awards for FY21 to faculty representing four departments. Two of the awards are collaboratively funded by the Department of Ophthalmology.

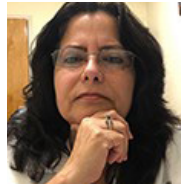
The awards provide up to \$40,000 to support junior faculty whose proposals are innovative, translational, interdisciplinary, and/or health disparities-oriented. Investigators go on to generate data for publications and external funding.



Roberta Brambilla, PhD

Associate Professor,
Neurological surgery

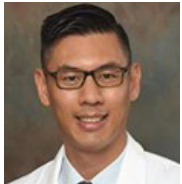
Investigation of oligodendrocyte-specific dysfunction in primary progressive multiple sclerosis



Delia Cabrera DeBuc, PhD

Associate Professor,
Ophthalmology

Investigating the role of gender and racial/ethnic bias in Artificial Intelligence's applications in ophthalmology



Ta Chen Chang, PhD

Associate Professor,
Ophthalmology

Geodemographic Analyses of Congenital Cataract Distribution



Andrew R Dykstra, PhD

Assistant Professor,
Biomedical engineering

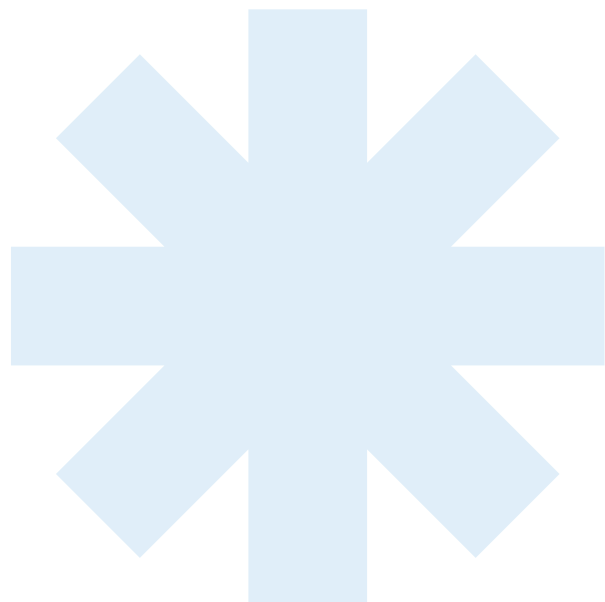
Effects of age on the neural basis of hearing in noise



Elizabeth Mahanna Gabrielli, PhD

Assistant Professor, Anesthesiology

Preoperative sleep disturbances and postoperative delirium in Latinos undergoing elective surgery: a Pilot Study



MIAMI CTSI FUNDING (All Sources)

\$6.5M FY21

\$54.2M Lifetime

CTSI FY21 INTERNAL AWARDS

5 PILOT AWARDS

PILOTS TOTAL FUNDING

\$200,000

LIFETIME ROI ON CTSI PILOT AWARDS

15:1

3 COVID-19 RAPID RESPONSE AWARDS

COVID-19 TOTAL FUNDING

\$200,000

U-LINK AWARD

\$50,000

Project Title:
Joint Academic Nurtureship for Underrepresented Students (JANUS): A Science Technology Engineering Arts and Mathematics (STEAM) Initiative



CTSI FY21 TEAM

45 FACULTY

58 STAFF

65 EXTERNAL COLLABORATORS

MS IN CLINICAL & TRANSLATIONAL INVESTIGATION

20  **4** 

FY21 ENROLLMENT FY21 GRADUATES

Over it's lifetime, 37 students have graduated from the Program; 92% graduates engaged in clinical/translational research

CAREER DEVELOPMENT/ KL2 PROGRAM

\$1M FY21 AWARDED SCHOLAR FUNDING

NEW SCHOLARS AWARDED IN FY21

3 NIH KL2 **1** INSTITUTIONAL

3 CONTINUING SCHOLARS FROM FY20

CTSI ENGAGEMENT*

2,710

* Number of instances or people who used at least one CTSI resource in FY21

RESEARCH USING ELECTRONIC MEDICAL RECORDS

409



FY21 EMR Clinical Data Requests

UNIVERSITY RESEARCH INFORMATICS DATA ENVIRONMENT (URIDE)

Deidentified EMR data resource

1.29M

UHealth patient records as of FY21

CONSENT TO CONTACT PROGRAM

123,000+

UHealth patients that agreed to be contacted for research by the end of FY21



44% FEMALE 56% MALE

27 Studies using Consent to Contact for Recruitment



CTSA NETWORK CLINICAL TRIALS IMPLEMENTED

7 Trial Innovation Network Trials as of FY2021

3 COVID-19 Network Trials

CTSI EDUCATION & TRAINING

87 FY20 Education & Training Events

1266 Total Attendees

BIostatistics Collaboration AND CONSULTING CORE

181 Core Users

34 Education Sessions

408 Attendees



FY21 PUBLICATIONS

Numerous publications resulted from CTSI-supported research in FY21.



91

CTSi-supported publications

Includes publications that cited the CTSI UL1 grant, used a CTSI resource, and by CTSI pilot awardees. Does not include COVID-19 publications.

77

Research, Condition, & Disease categories*

173

Citations

121

News media mentions

*A publication can belong to more than one category.



51

CTSi Career Development Scholars Research Publications

Includes active and recently graduated KL2 and institutional scholars.

116

Citations

32

News media mentions



83

COVID-19 publications by CTSI researchers

Includes COVID-19 publications that used a CTSI resource or were by CTSI awardees. Not counted above in "CTSi-supported publications".

817

Citations

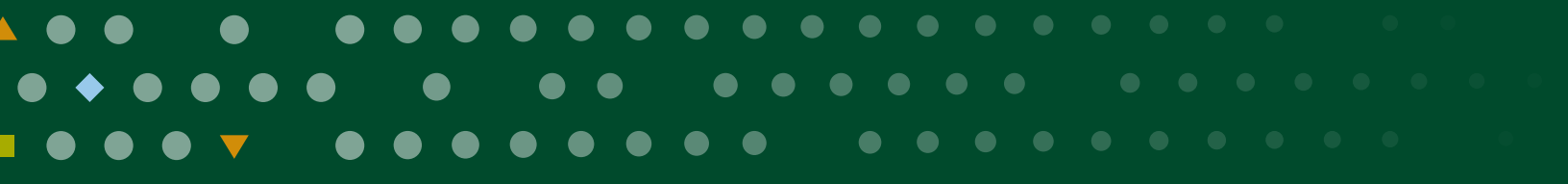
669

News media mentions



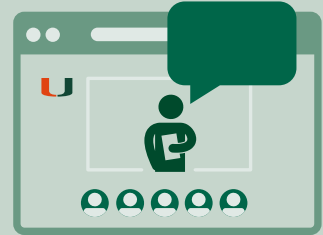
2021 HIGHLIGHTS AND ACHIEVEMENTS

A look back at the year's highlights and achievements across education and training, stakeholder engagement, health research and our continuing response to COVID-19



EDUCATION & TRAINING

CTSI offers a diverse range of interdisciplinary clinical and translational research education and training opportunities to faculty, staff, and students. In FY21, these events were conducted virtually.



TRAININGS, WORKSHOPS & SEMINARS

408

Total Attendees

**BIostatISTICS
ROUNDTABLES, CLINICS
AND REDCAP TRAININGS***

224

Total Attendees

CONNECTION SEMINARS*

414

Total Attendees

**DEAN HENRI R. FORD'S
INTERDISCIPLINARY
RESEARCH SEMINAR SERIES***

32

Total Participants

**GRANT WRITING
SUPPORT**

21

Total Trainees

**I-CORPS ENTREPRENEURSHIP
TRAINING COURSE**

335

Total Attendees

**INFORMATICS WORKSHOPS
AND SEMINARS***

1,049

Total Attendees

**NETWORK OF CLINICAL
RESEARCH PROFESSIONALS
SEMINAR SERIES***

40

Total Trainees

**RESEARCH MENTORING
TRAINING WORKSHOP**

131

Total Trainees

**RESEARCH REGULATORY
TRAINING***

1,494

Total Attendees

**TRANSLATIONAL TUESDAYS
SEMINAR SERIES***

*Recurring series

EDUCATION & TRAINING

TRANSLATIONAL RESEARCH SEMINARS

The Dean Henri Ford’s Interdisciplinary Research Seminar Series (DIRSS) features successfully funded interdisciplinary team of scientists and stakeholders who collaborate on translational projects.

The CTSI Translational Tuesday (TT) COVID-19 seminar series is a forum for clinicians and interdisciplinary research teams to present their COVID-19 work. The series highlighted COVID-19 research and clinical trials being conducted at University of Miami.

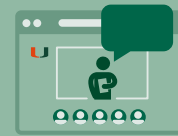
NETWORK OF CLINICAL RESEARCH PROFESSIONALS (NCRP)

CTSI’s seminar series is a forum for clinical research professionals to learn about research units across UM, clinical research policy and process updates, best practices, and to network with peers.

Seminar topics in FY21 also covered electronic regulatory binders, electronic consent for research and how to conduct clinical research effectively during the pandemic.

BIOSTATISTICS CLINICS AND ROUNDTABLES

The clinics and roundtables conducted by the Biostatistics Collaboration and Consulting Core provide ongoing education in biostatistics to the research community. The clinics address specific statistical topics and the roundtables provide an interactive and collaborative forum for discussion among investigators about general statistical issues in research.



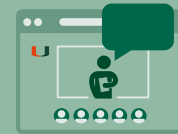
6

DIRSS Seminars



12

TT Seminars



10

Seminars



400

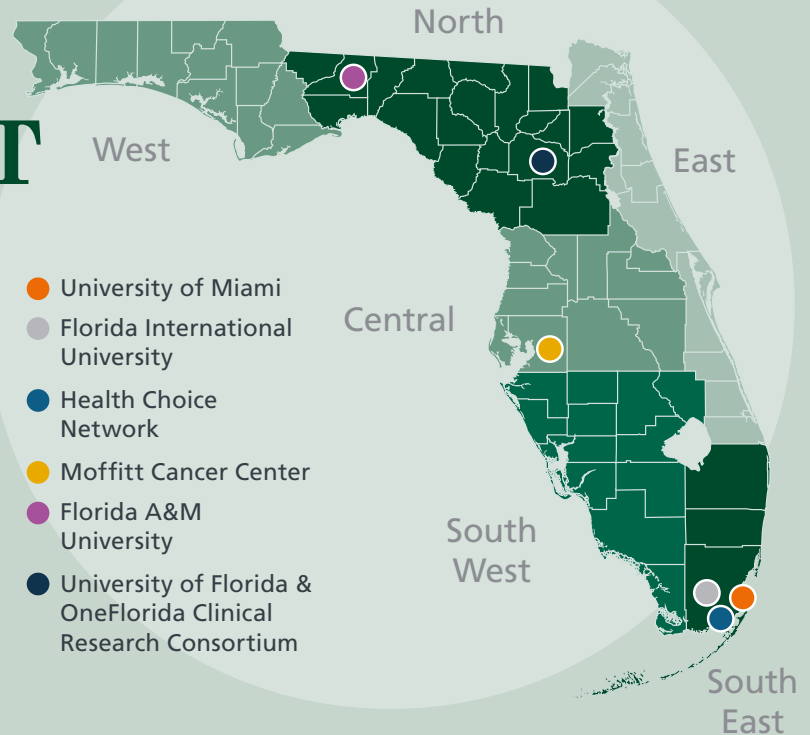
NCRP subscribers



34

Biostatistics education events

COMMUNITY ENGAGEMENT



CTSI FACILITATES COVID-19 COMMUNITY ENGAGED RESEARCH, DISSEMINATION, & OUTREACH

Funded by a **\$1.69M** award by NIH’s national CEAL Alliance Program, the FL-Community-Engagement Research Alliance (FL-CEAL) Against COVID-19 in Disproportionately Affected Communities is a statewide collaborative outreach program to engage ethnic and racial minority communities affected by the COVID-19 pandemic. This multi-PI statewide initiative is led by CTSI’s **Community and Stakeholder Engagement Program** Co-Director, Dr. Olveen Carrasquillo and managed by the Miami CTSI.

FL-CEAL MINORITY COMMUNITIES SERVED

- Latinx communities in Miami-Dade County: rural agricultural, urban low income, sexual/gender minorities
- Underrepresented minority communities in South FL (Black, elderly)
- Rural minority communities in north-central & north-eastern FL, & the FL panhandle
- West-central and western FL vulnerable communities

FL-CEAL FOCUS AREAS


COVID-19 education

700+ 

Surveys to identify COVID-19 knowledge, & barriers/facilitators in clinical trial participation

200+

Outreach activities to promote evidence-based health promotion practices, address vaccine hesitancy

51 

CEAL resources on COVID-19 basics, diversity & inclusion


31,544

Community members reached

540

Outreach workers supporting FL-CEAL activities

Vaccine Resources

39 

CEAL vaccine videos, toolkits, websites, fact sheets

Diversity & Inclusion in Clinical trials

COVID-19 vaccine and therapeutic trials at FL-CEAL sites (Univ of Miami, Univ of Florida) **achieved higher minority participation** than the national average



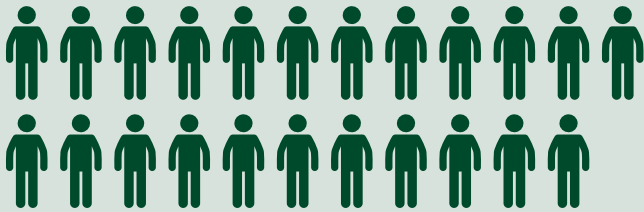
40

Webinars/panels conducted

CLINICAL RESEARCH

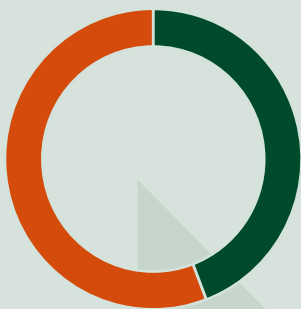
PATIENT RECRUITMENT INTO RESEARCH STUDIES

CTSI'S Consent to Contact Program has enabled creation of a database of UHealth patients who have agreed to be contacted for research studies. Researchers can access patient contact lists through an established process for their IRB-approved studies.



123,000+

Patients in Consent to Contact Database as of FY21



56%
MALE

44%
FEMALE

Race/
Ethnicity under-
represented
in research

43%
HISPANIC

13%
BLACK/AFRICAN
AMERICAN

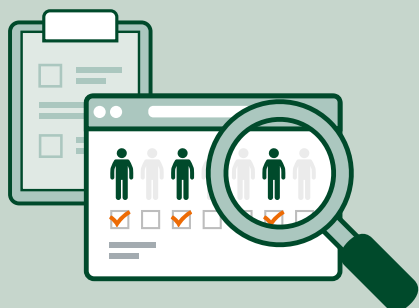
20

Research studies
in FY21 that
used Program

COMMUNITY PARTICIPANT RECRUITMENT FOR RESEARCH

The University of Miami Health Research Portal, a public-facing website that features UM health research studies, was launched in October 2020. The site allows potential volunteers, including healthy participants, to search for studies using lay-friendly key words and for study teams to connect with participants.

<https://umiamihealthresearch.org/>

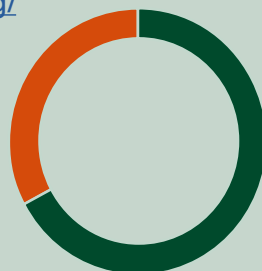


133

Research studies listed

581

Volunteers



33%
MALE

67%
FEMALE

Race/
Ethnicity under-
represented
in research

41%
HISPANIC

3%
BLACK/AFRICAN
AMERICAN

PILOT AWARD SPOTLIGHTS

Miami CTSI's extremely successful Pilot Translational and Clinical Studies Program has funded innovative scientific projects with demonstrated/potential health and societal benefits*

*Translational Science Benefits Model, 2018

SPOTLIGHT PROJECT TITLE

The 90 DAYS Entertainment Education Trial to increase HIV status disclosure, self-report medical adherence, and reduce perceived HIV stigma.

PROJECT TEAM



Nick Carcioppolo, PhD,
Associate Professor, Department of
Communication Studies, School of Communication,
University of Miami (PI)



JoNell Potter, RN, PhD, FAAN,
Professor, Department of Obstetrics and
Gynecology, University of Miami, School of
Medicine (Co-I)



Jazmyne Simmons, PhD, MPH
Visiting Instructor, School of Allied Health Sciences,
Florida A&M University, (Co-I)



SUMMARY

The Southern U.S. is disproportionately impacted by the HIV epidemic. While accounting for 38% of the U.S. population, the South represents nearly 51% of new annual HIV diagnoses. Of particular concern, Black women in the South account for 67% of all newly diagnosed HIV cases among women. Living with HIV presents myriad challenges in fostering and maintaining healthy intimate partner relationships, including complexities related to status disclosure, medical adherence, and stigmatization. Disclosure avoidance can place sexual partners at increased risk of HIV. Extant interventions rarely address intimate partner status disclosure, a primary recommendation to increase safer sex practices among persons living with HIV. Current strategies have neglected the influence of HIV internalized stigma on disclosure which impedes intimate partner status disclosure and reduces safer sex practices. Intimate partner disclosure avoidance can result in negative psychological and medical consequences such as reduced medical adherence.

Guided by the disclosure process model and entertainment education theory, this investigation sought to understand whether and how a short entertainment film about a new relationship and HIV status disclosure, 90 DAYS, could be used as an intervention to address HIV-related stigma, intimate partner status disclosure, and self-report HIV medical adherence among Black HIV positive women.

SIGNIFICANCE

An important strategy to reduce HIV transmission is medical adherence and status disclosure among sexual partners. Status disclosure is a crucial method of primary prevention, as it increases discussion and implementation of prophylactic prevention measures. Equally important is disclosure can improve medical adherence; a pillar in reducing the HIV/AIDS epidemic.

This pilot investigation is the first randomized controlled trial to empirically investigate the effectiveness of an entertainment education intervention to address HIV-related outcomes among Black women living with HIV. This transdisciplinary project combined the theoretical approaches of entertainment education and the disclosure process model to understand the process through which exposure to an entertainment film about HIV status disclosure can impact perceptions of internalized stigmatization, self-report medical adherence intentions, and HIV status disclosure intentions.







The study compared the entertainment film to a standard-of-care control brochure designed to teach best practices for HIV status disclosure. Results suggest that the 90 DAYS film significantly outperformed the control condition on a variety of outcomes. Exposure to the film resulted in stronger disclosure beliefs, positive disclosure attitudes, disclosure self-efficacy, and disclosure intentions compared to the standard-of-care brochure. Further, in comparison to the brochure condition, those who watched the film were significantly more likely to report that their stimulus (i.e. 90 DAYS) could be used as a tool to aid in safer disclosure events. Lastly, across conditions, there were no statistically significant differences in internalized stigma, medical adherence intentions, or anticipated stigma. These results highlight the utility of using an entertainment education intervention as a tool to increase attitudes, beliefs, and intentions around HIV status disclosure. Compared to existing interventions, the proposed study can have a substantial public health impact due to its expansive reach and can be translated to other HIV populations.

BENEFITS

This research has community/public health, economic, and policy implications. The framework for these implications was derived from the Translational Science Benefits Model created by the Institute of Clinical & Translational Sciences at Washington University in St. Louis.

Demonstrated benefits are those that have been observed and are verifiable.

Potential benefits are those logically expected with moderate to high confidence.

| BENEFIT | DOMAIN | BENEFIT (INDICATOR) |
|---|--|--|
| The film led to stronger disclosure beliefs, positive disclosure attitudes, disclosure self-efficacy, and disclosure intentions compared to the standard-of-care brochure. Demonstrated. |  COMMUNITY | Health Education Resources |
| Study findings being disseminated through participation in three advisory committees at the local and state level. Demonstrated. |  POLICY | Committee Participation |
| Increased HIV status disclosure can enable access to services and care and decrease HIV rates that would benefit the community. Potential. |  COMMUNITY | Community Health Services |
| HIV status disclosure can lead to greater adherence to HIV care and treatment. Potential. |  COMMUNITY | Diseases prevention & reduction |
| Timely access to HIV care and treatment, improved mental & physical health. Potential. |  COMMUNITY | Life Expectancy & Quality of Life |
| Reducing the individual burden of long-term HIV treatment through decreasing the transmission rates of HIV, improved health can reduce community burden and reduce healthcare costs in the long-term. Potential. |  ECONOMIC | Societal & Financial Cost of Illness |

Community and Public Health Benefits of the 90 DAYS Entertainment Education Trial can be seen in several ways. The trial established Entertainment Education (EE) as an effective strategy to address HIV stigma, disclosure and medical adherence. EE led to stronger disclosure beliefs, positive disclosure attitudes, disclosure self-efficacy, and disclosure intentions compared to the standard-of-care brochure. The tool, tested with Black women with HIV, can be used as an interventional educational resource for other HIV populations. Other potential benefits include timely access to HIV care and treatment, greater adherence to HIV care and treatment, and improved community health outcomes.

Policy: The study has potential policy implications. Dr. Simmons serves on the Tallahassee-Leon Commission on the Status of Women and Girls and uses evidence-based research to advocate for programs and policies that protect and improve the health of local women and girls. Dr. Simmons also serves on the Florida Healthy Youth Alliance which advocates for comprehensive sexual health education within the Florida public school system, and on the Carlos Alvarez HIV Communications Review Panel overseen by the Florida Department of Health. The positive study findings can be used as evidence to advocate for EE as an educational intervention resource in programs supported by these committees.

Economic: In the long-term, the study has potential economic benefits by reducing the individual burden of long-term HIV treatment through decreasing the transmission rates of HIV thereby reducing healthcare costs.

SPOTLIGHT PROJECT TITLE

Objective Behavioral Measurement to Address Health Disparities in Autism Spectrum Disorder (ASD) Diagnosis

PROJECT TEAM



Lynn Perry, Ph.D.,
Associate Professor,
Department of Psychology,
University of Miami (Co-PI)



Daniel Messinger, Ph.D.,
Professor,
Department of Psychology,
University of Miami (Co-PI)



SUMMARY

Autism spectrum disorder (ASD) is a highly prevalent disorder characterized by social communication disturbances. Early ASD diagnosis and intervention are essential for achieving positive health outcomes. However, there are disparities between Latino and non-Latino children with ASD in the time to diagnosis, creating long-term public health burdens. This project objectively measured social communication behaviors (smiles, vocalizations) of Latino and non-Latino children in different contexts (home, clinic) to predict clinician and parent perceptions of ASD symptoms. By identifying behaviors associated with individual children's strengths and difficulties, the project shed light on the sources of health disparities in ASD diagnosis.

The goal of the project is to utilize objective measurements to assess the stability of social communication in Latino and non-Latino children with ASD to determine how differences in patterns of ASD behavioral expression contribute to ethnic disparities in diagnoses. We hypothesize greater variability in objectively measured social communication behaviors across contexts for Latino than non-Latino children.

This project brought together researchers from Psychology, Physics, and Electrical and Computer Engineering as well as the Center for Autism and Related Disabilities to understand how social communication behaviors vary across individuals with autism spectrum disorder.

SIGNIFICANCE






Autism spectrum disorder (ASD) is defined by observed social communication disturbances across multiple contexts. ASD is a common developmental disorder with 1 in 59 children having a diagnosis and related societal costs are \$35 billion annually. However, current diagnostic practices are associated with disparities in time-to-diagnosis and diagnostic accuracy, which negatively impact Latino children. Non-Latino white children are diagnosed by 4 years of age while Latino children are not diagnosed until about 8 years of age. This suggests that we need a system to better understand ASD symptoms to make accurate timely diagnoses to increase early intervention. In practice, diagnosis is often restricted to clinician observation in the context of the Autism Diagnostic Observation Schedule (ADOS) assessment and the Autism Diagnostic Interview – Revised (ADI-R) parent interview. As early detection and diagnosis of ASD is vital for accessing early intervention and achieving positive developmental outcomes, it is critical to understand the origin of these disparities in diagnoses between Latino and non-Latino children.

BENEFITS

This research has clinical, community, and economic implications. The framework for these implications was derived from the Translational Science Benefits Model created by the Institute of Clinical & Translational Sciences at Washington University in St. Louis.

Demonstrated benefits are those that have been observed and are verifiable.

Potential benefits are those logically expected with moderate to high confidence.

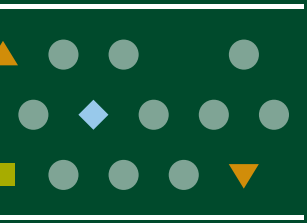
| BENEFIT | DOMAIN | BENEFIT (INDICATOR) |
|---|---|--|
| Development of a multimodal autism assessment process with motion tracking, video, and audio. Demonstrated. |  CLINICAL | Investigative Procedures |
| Development of software and algorithms for data annotation and analysis of multimodal data. Demonstrated. |  CLINICAL | Software Technologies |
| Development of improved procedures for early ASD diagnosis by reducing disparities in diagnosis. Potential. |  CLINICAL | Diagnostic Procedures |
| Early intervention and better outcomes in Latino children due to earlier ASD diagnosis. Potential. |  COMMUNITY | Health Care Accessibility |
| Better outcomes due to early intervention strategies would alleviate the burden on community resources. Potential. |  ECONOMIC | Societal & Financial Cost of Illness |

Clinical: Drs. Messinger and Perry along with their team have developed a procedure for collecting continuous multimodal data from audio, video, and movement, to understand associations between social communication behaviors and children’s clinician-informed symptom severity. They have also developed software and algorithms to annotate and analyze this multimodal data.

This research has the potential to impact the procedures used in ASD diagnosis to facilitate early detection and intervention, with better outcomes. This project utilized reproducible methods to produce objective measurements of the social communication patterns of children with autism spectrum disorder (ASD). Social communication was assessed with the parent and a clinician in the clinic during administration of the ADOS assessment, which is the current gold standard in ASD diagnosis. The methods and materials from their research will be released to investigators to expand the clinical and intellectual impact of the project to other researchers and clinicians both nationally and internationally.

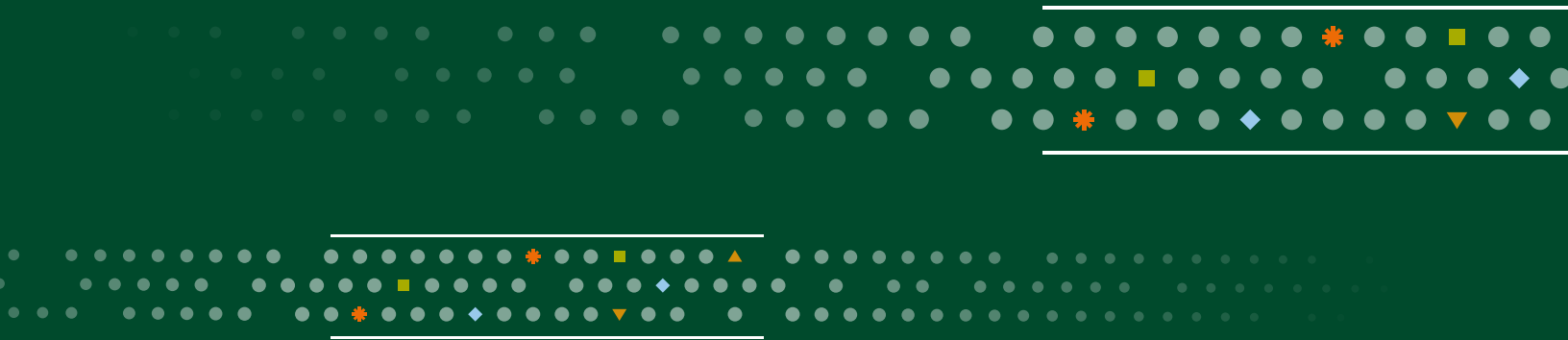
Community: This study highlights the disparities that exist between diagnosis age of Latino vs. non-Latino children and its findings have immediate benefits to the children being assessed for ASD, their families, as well as to the clinicians making autism diagnosis. By highlighting this disparity, the study will also potentially impact health care accessibility and equity by promoting new healthcare strategies that would allow children diagnosed with ASD the opportunity to receive timely services and improve the quality of life for patients and their families.

Economic: The study has potential long-term economic benefits that include cost savings and effectiveness post ASD treatment and intervention. These benefits may result from reductions in other service use and associated costs, thereby reducing undue societal and community burden and allowing for reallocation of resources.



YEAR IN REVIEW

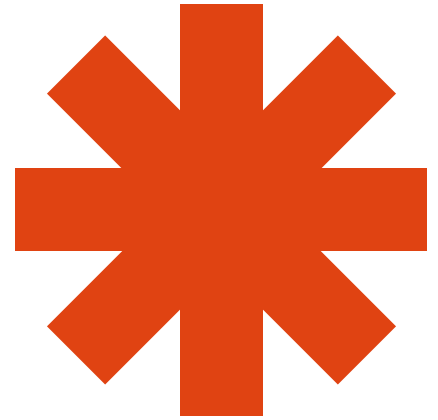
Selected highlights from FY21 events
and activities



YEAR IN REVIEW

CTSI EXTERNAL ADVISORY COMMITTEE MEETING

The Miami CTSI hosted its first all-virtual External Advisory Committee (EAC) Meeting on February 24, 2021. The seven-member committee is comprised of leaders from U. California Davis, Columbia U., Emory U., U. Florida, and Parent Project Muscular Dystrophy. The CTSI received positive feedback from the committee in demonstrating its achievements over the past year.



I-CORP@NCATS ENTREPRENEURSHIP COURSE

The I-Corps@NCATS short course was conducted in Fall 2020 and Spring 2021 and led by Suhrud Rajguru, PhD, Associate Professor and CTSI Assistant Director for the Collaboration and Multidisciplinary Team Science Program. In FY21, 17 teams from 5 universities participated in the course. Notable outcomes from the course include teams establishing startups and progressing to SBIR/STTR funding mechanisms.

RESEARCH MENTORING WORKSHOP

The second mentor-mentee training program was conducted successfully with 21 mentor-mentee teams representing 14 fields participating in the workshop. The three-part workshop was conducted in collaboration with the U. Colorado CTSA Program and UM co-directors Alessia Fornoni, MD PhD, Maria Alcaide, MD, and Robert Levy, PhD. Dr. Fornoni is also the Co-Director of CTSI's Translational Workforce Development and the KL2 Programs.



GRANT WRITING SUPPORT

The Miami CTSI in collaboration with the Miller School of Medicine's (MSOM) Executive Dean for Research Office and the Office of the Vice Provost for Research + Scholarship implemented a grant support service through Hanover Research, a grant development firm. This resource is available to early career faculty applying for a first-time grant or resubmission and research teams applying for large grants.

SELECTED CTSI AWARDEES' ACHIEVEMENTS IN FY21

Suhrud Rajguru, PhD, Associate Professor of Biomedical Engineering and Otolaryngology, Assistant Director of CTSI's Collaboration and Multidisciplinary Team Science Program and past pilot program awardee received three grants including NIH R01 and SBIR awards with more than \$2.3M in total funding.

Alberto Ramos, MD, MSPH, Associate Professor of Neurology, CTSI KL2 Graduate, and Research Director of the Sleep Disorders Program, was awarded a five-year \$13 million grant from the National Institute on Aging to study the impact of obstructive sleep apnea on the risk of Alzheimer's disease and other dementias in Hispanic adults.

PUBLIC VOICES FELLOWSHIP

CTSI-sponsored Public Voices Fellow Dr. Teshamae Monteith published 6 op-ed pieces over the course of the 12-month University of Miami Public Voices fellowship with one of her pieces on plant-based diets garnering over 650 shares. Her op-eds were published in The Hill, U.S. News, and The Miami Times among other media. The goal of the national OpEd Project's Public Voices Fellowship is to dramatically increase the public impact of the nation's top underrepresented thought leaders including women, and to ensure their ideas help shape important conversations in today's age. University of Miami joined the program in 2020.

URIDE AND DATA WAREHOUSE

CTSI's University Research Informatics Data Environment (URIDE) is a web-based platform that visualizes aggregated de-identified data from the UHealth UChart system and enables researchers to query the data for feasibility analysis and other applications. As of FY21, the interactive database had demographics and health data from 1.29M+ UHealth patients, and over 215 users.

University of Miami investigators can request specific clinical data sets for research by directly submitting requests through a self-service portal or Information Technology helpdesk. In FY21, 409 data requests were processed through the clinical data warehouse mechanism.

CTSI CONSORTIUM ACTIVITIES

The Miami CTSI participated in several consortium level activities in FY21. Highlights include:

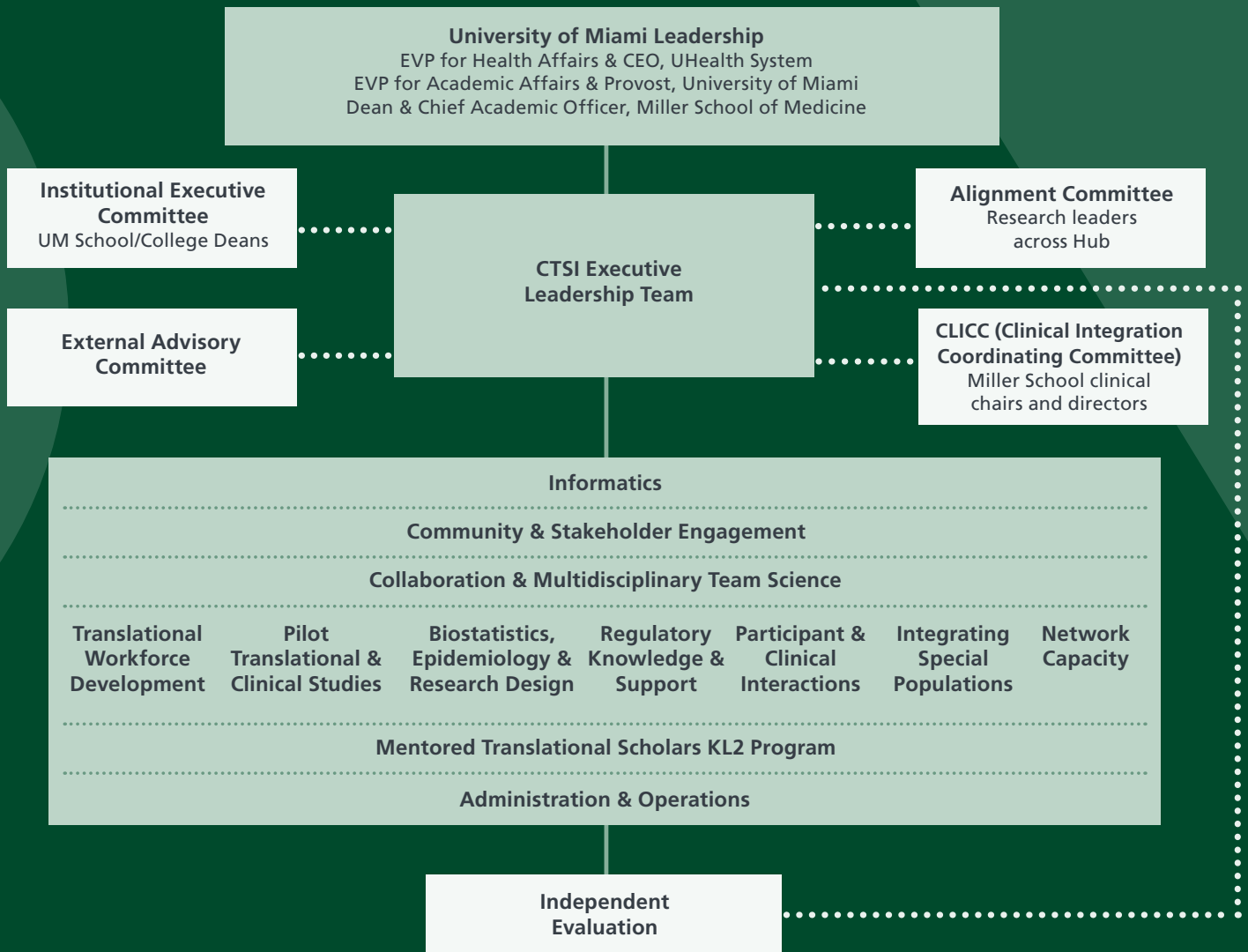
- Co-authored 3 publications with CTSA consortium institutions.
- Participated in and led 4 writing groups for the Journal of Clinical and Translational Science COVID-19 special issue: N3C and role of informatics, community engagement, health disparities, and prioritizing studies of COVID-19.
- Transmitted 26k unique records to the NCATS-funded National COVID-19 Cohort Collaborative, a centralized national data resource for COVID-19 research. Through a data use agreement finalized in October 2020, UM researchers can access the national dataset by submitting or joining a project.
- Conferences
 - Association for Clinical and Translational Science (ACTS) Translational Science 2020 conference panel: "I-Corps@NCATS - Research Translation Through Commercialization".
 - ACTS Translational Science 2021 conference posters on community engagement and evaluation topics.

INSTITUTIONAL PARTNERSHIP

The Miami CTSI actively works with University of Miami leaders to align with Miller School of Medicine, UHealth System, and University research strategic plans. To that end, the CTSI formally reports to University of Miami academic and health system leaders, providing bidirectional, dynamic feedback and mutual prioritization of research focus areas and activities.

In addition to funding from the National Center for Advancing Translational Sciences, in FY20 the Miami CTSI was supported by UHealth System and Miller School of Medicine leadership, as well as the University of Miami Provost.

FY21 CTSI STRATEGIC STRUCTURE



CTSI GOVERNANCE

INSTITUTIONAL EXECUTIVE COMMITTEE

- Roni Avissar**
(Dean, RSMAS)
- Leonidas Bachas**
(Dean, Arts & Sciences)
- Victoria Behar-Zusman**
(Associate Dean for Research, Nursing & Health Studies)
- Daniel Berg**
(Research Professor, Engineering)
- Norma Kenyon**
(Vice Provost, Innovation)
- Erin Kobetz**
(Vice Provost, Research)
- Laura Kozma**
(Associate Vice President Research Administration)
- Guillermo Prado**
(Vice Provost, Faculty Affairs & Dean, Graduate School)

FY21 CTSI EXECUTIVE LEADERSHIP TEAM

- Ralph L. Sacco**
(PI & Director)
- Jonelle Wright**
(Co-I, Assoc Director)
- W.Dalton Dietrich**
(Co-I, Assoc Director)
- Dushyantha Jayaweera**
(Co-I, Assoc Director)
- Sheela Dominguez**
(Strategic Operations)
- Daru Ransford**
(Business Operations)

ALIGNMENT COMMITTEE

- Katuska Barbery**
(Director, Clinical Research, Jackson Health System)
 - Erin Kobetz**
(Vice Provost, Research)
 - Peter Paige**
(Chief Clinical Officer/Chief Physician Executive, Jackson Health System)
 - Carl Schulman**
(Executive Dean, Research Miller School of Medicine)
 - José Szapocznik**
(CTSI Founding PI)
- CTSI Executive Leadership Team**

CLINICAL INTEGRATION COORDINATING COMMITTEE

- Maria T. Abreu**
(Vice-Chair for Research, Medicine)
 - Eduardo Alfonso**
(Chair, Ophthalmology)
 - Joshua Hare**
(Director, Interdisciplinary Stem Cell Institute)
 - Erin Kobetz**
(Vice Provost, Research)
 - Stephen Nimer**
(Director, Sylvester Comprehensive Cancer Center)
 - Michael Paidas**
(Chair, Obstetrics & Gynecology)
 - Vittorio Porciatti**
(Vice-Chair for Research & Director, McKnight Vision Research Center)
 - Judy Schaechter**
(Chair, Pediatrics)
 - Fred Telischi**
(Chair, Otolaryngology)
 - Omaida Velazquez**
(Chair, Surgery)
 - Roy Weiss**
(Chair, Medicine)
 - Stephan Züchner**
(Chair, Human Genetics)
- CTSI Executive Leadership Team**

EXTERNAL ADVISORY COMMITTEE FY21

- Patricia Ann Furlong, MS**
Founder, President & CEO, Parent Project Muscular Dystrophy
- Jill G. Joseph, MD, PhD, MPH**
Professor Emeritus, University of California Davis Betty Irene Moore School of Nursing
- Duane Mitchell, MD, PhD**
Associate Dean, University of Florida College of Medicine; Director, UF Clinical and Translational Science Institute

- David Nelson, MD**
Senior Vice President for Health Affairs, University of Florida, President, UF Health
- Harold Pincus, MD**
Associate Director, Irving Institute for Clinical and Translational Research; Professor and Vice Chair, Department of Psychiatry, Columbia University; Director of Quality and Outcomes Research, New York-Presbyterian Hospital

- David S. Stephens, MD**
Chair, Department of Medicine, Stephen W. Schwarzmann Distinguished Professor of Medicine, Emory University School of Medicine; Vice President for Research, Woodruff Health Sciences Center, Emory University

ACKNOWLEDGMENTS

CTSI PROGRAM LEADERS

Daniel Armstrong, PhD
Olveen Carrasquillo, MD, MPH
Shari Messinger Cayetano, ME, PhD
Sylvia Daunert, PharmD, PhD, MS W.
Dalton Dietrich, PhD
Alessia Fornoni, MD, PhD Dushyantha Jayaweera, MD
Norma Kenyon, PhD
Erin Kobetz, PhD, MPH
David Loewenstein, PhD
Suhrud Rajguru, PhD
Sunil Rao, PhD
Tatjana Rundek, MD, PhD
Ralph L. Sacco, MD, MS
Carl Schulman, MD, PhD, MSPH, FACS
Gwendolyn Scott, MD
Nick Tsinoremas, PhD
Jonelle Wright, PhD

CTSI OPERATIONS PERSONNEL

| | |
|----------------------|-----------------|
| Patricia Avissar | Gigi Giobio |
| Caprice Battle | Enjoli Johnson |
| Stellamarina Covelli | Chin-Chin Lee |
| Rosalina Das | Raquel Perez |
| Marisabel Davalos | Deepthi Puram |
| Jessica Diaz | Daru Ransford |
| Sheela Dominguez | Peyman Taghioff |

C/T RESEARCH INFRASTRUCTURE

- Biostatistics Consultations
- Consent to Contact Program
- Feasibility Analysis & Cohort ID Tools
- Network Trial Operations
- One Florida Research Consortium
- Pilot Grants
- REDCap Database Support
- Regulatory Consultations
- Research IT & Data Storage Tools
- Research Navigator
- Research Training Center
- Research Writing Support
- COVID-19 Research Facilitation

TRANSLATIONAL WORKFORCE DEVELOPMENT

- Biostatistics Education
- C/T Research Workshops
- The Connection
- Commercialization Seminar Series
- Grant Writing Support & Consultations
- I-Corps Training Program
- Informatics Training
- KL2 Program
- Master's Program
- Network for Clinical Research Professionals
- Research Mentoring Training Program
- Team Science Seminars

STAKEHOLDER ENGAGEMENT AND CULTURALIZATION

- Community Engagement
- Community Health Workers Training
- Health Disparities Focus
- Lifespan Study Consultations
- Study Recruitment:
 - Consent to Contact Program
 - ResearchMatch
 - UMiami Health Research portal

For a comprehensive list of resources, visit www.miamictsi.org