OneFlorida Clinical Research Consortium

Building a Statewide Partnership for Patient Centered Research

Why a OneFlorida Partnership?

10 MILLION PATIENTS • 4,100 PHYSICIAN PROVIDERS • 1,240 PRACTICES/CLINICS • 22 HOSPITALS • 67 COUNTIES
17 Years

Research to Reality

? ? ?

Rural Residents, Serious Mental Illness, Children, Older Adults

33%

Women's participation in clinical trials

5% to 15%

African-American participation in clinical trials

1% to 7.6%

Hispanic participation in clinical trials

Disproportionate Disease Burden

Not Representative of the Population

Some Questions On the Institute of Medicine Top 100 Priorities and Many Remain Unanswered

Colorectal Cancer Screening

Should I and how often should I have colorectal cancer screening

Dementia

What are the best pharmacologic and non-pharmacologic interventions for individuals with dementia who are living at home with their caregivers?

Hypertension

What are the appropriate levels of blood pressure control? For African Americans? Hispanics? White non-Hispanics?
Create an Enduring Infrastructure For

- Cohort Discovery
  - Inclusive of Diverse Populations
- Comparative Effectiveness Research
  - What Works Better for Whom Under What Circumstances?
- Pragmatic Clinical Trials
  - Conducted in Real World Settings to Accelerate Translation to Practice and Adoption
- Implementation Science Studies
  - The Science of Fostering the Uptake of Evidence-Based Best Practices Into Diverse Health Care Settings

Statewide Partners

- University of Florida and UF Health
- Florida State University and the Regional Campus Practice Partners
- University of Miami and UHealth
- Orlando Health
- Florida Hospital
- Tallahassee Memorial HealthCare
- Health Choice Network
- Bond Community Health Center Inc.
- Miami Children’s Health System
- WellFlorida Council
The University of Florida, the University of Miami and Florida State University unite health systems, health plans, providers and patients to form the OneFlorida Clinical Research Consortium.

The OneFlorida Cancer Control Alliance strengthens statewide infrastructure to reduce disparities in cancer control and prevention with funding from the James and Ester King Biomedical Research Program.
The Patient-Centered Outcomes Research Institute approves a funding award designating the OneFlorida Clinical Research Consortium as one of 13 clinical data research networks nationwide.

PCORnet Partners

- Accelerating Data Value Across a National Community Health Center Network (ADVANCE)
- University of Chicago: Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)
- Greater Plains Collaborative (GPS)
- Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) Network
- Mid-South CORN
- PaTH: Towards a Learning Health System
- Louisiana CDRN (LACDRN)
- National Pediatric Health Learning System (PEDSnet)
- New York City Clinical Data Research Network (NYC-CDRN)
- Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)
- Patient-oriented SCAlable National Network for Effectiveness Research (pSCANNER)
- Patient-Centered Network of Learning Health Systems (LHSNet)
- OneFlorida Clinical Data Research Network

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Scientific Advisory Committee

Peter J. Embi, M.D., M.S., F.A.C.P., F.A.C.M.I.
Associate Professor and Vice Chair, Department of Biomedical Informatics
Division Director, Division of Clinical and Translational Informatics
Chief Research Information Officer, Wexner Medical Center
Associate Dean for Research Informatics, College of Medicine
Physician, Department of Internal Medicine, Division of Rheumatology & Immunology, The Ohio State University

Electra Paskett, Ph.D.
Marion N. Rowley Designated Chair in Cancer
Professor of Cancer Research,
Division of Cancer Prevention and Control,
Department of Internal Medicine, College of Medicine,
The Ohio State University

Ross Brownson, Ph.D.
Director, Prevention Research Center
Washington University in St. Louis

Albert W. Wu, M.D. M.P.H., F.A.C.P.
Director, Center for Health Services and Outcomes Research
Director, Ph.D. Program in Health Services Research & Policy
President-Elect, Faculty Senate
Johns Hopkins Bloomberg School of Public Health

ONEFLO RIDA
STEERING COMMITTEE

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Programs and Workgroups

**Integrated Clinical Research Program**
- Carolee, William Hogan, Nick Tsinoremas, Thomas Robinson, Al Phalp
- Community Clinician/Health Systems Engagement Practice Facilitation Integration, Implementation, and MoC Multi-Network Study Support Minority Education Program

**Data Trust Program**
- William Hogan, Nick Tsinoremas, Thomas Robinson, Al Phalp
- Data Query & Analytics Honest Brokers PROs IT

**Patient Population Program**
- Rhonda Cooper-DeHoff, Joe Nadglowski, Carlos Maeztu, Myrtle Graham, Krista Vandenborne, Barry Byrne, Al Frase
- Hypertension Obesity
- DMD Rare Disease Tobacco Cessation

**Patient and Citizen Scientist Program**
- Olveen Carrasquillo, Linda Cutler, Carlos Maetzu
- Participant Recruitment Information Dissemination

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Integrated Clinical Research Program

**Recruitment**
Health care settings, clinicians, community settings

**Involvement**
Community clinicians
On the Road Design Studios
Translational and Implementation Science Studios

**The Learning Health System**
Maintenance of Certification
Integration into Workflow
Engagement

**Expansion**
Plans are in place to expand clinician engagement across the state and infrastructure support to partner institutions.

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Cohort Development and Computable Phenotypes

**Obesity**
Focus: Diversity in Obesity — Factors related to the development, prevention, and treatment of obesity in diverse populations, including but not limited to race/ethnicity, age, socioeconomic status, sex, and geographic area.
Computable Phenotype: Defining Healthy Obesity; Early Childhood Obesity (in progress); Severe Obesity: Pediatric and Adult (in progress); Obesity Treatment: Pediatric and Adult (in progress)
Next Steps: Participating in two PCORnet obesity studies; defining and developing two study proposals based on computable phenotypes

**Duchenne Muscular Dystrophy**
Focus: Submitting the Bone Health Study to PCORI
Computable Phenotype: Individuals with Duchenne Muscular Dystrophy
Next Steps: A possible collaboration with PPMD, Duchenne Connect, the CDC, and the University of South Carolina

**Hypertension**
Focus: Identifying characteristics that predict resistant hypertension and assessing CV risk associated with multiple achieved BP targets
Computable Phenotype: Adults with 1) treatment resistant hypertension and 2) hypertension with or without diabetes associated CV outcomes
Next Steps: Deploy and refine algorithms to identify cohorts and then perform analyses
The Citizen Scientist Program

Recruitment
The team has grown from six community members to 11, ranging in age from early 20s to mid-80s and representing a variety of cultural perspectives.

Involvement
The Citizen Scientists are fully integrated into the consortium's infrastructure and have served on a variety of work groups and provided community member feedback on more than five proposals since September.

Expansion
Plans are in place to expand community engagement across the state and infrastructure support to partner institutions.

The OneFlorida Data Trust

DATA
Florida Medicaid and Medicare*, Florida Cancer Registry and Florida Vital Statistics with Identifying Information
Limited Data Sets from EHRs from Clinical Partners
Patient Consent for Registry and/or Study Participation
PROs and Other Study Data Collection

ACCESS
OneFlorida Research Mart
OneFlorida Data Trust Query
Submit Protocol to OneFlorida IRB and Steering Committee

* Florida Medicare Pending

1. OneFlorida Data Trust Query
2. Success
3. Approval
4. Data Provided

Limited Data Set

OneFlorida Data Trust

Data Capture Strategies
ETL Processed and Tablet-Based Electronic Systems
Local Honest Brokers for Limited Data Sets IDs and/or Patient Contact Info

* Florida Medicare Pending
Accomplishments

- MOU / DUA Agreements Complete
  Orlando Health, Tallahassee Memorial Health Care, UF Health, Bond Clinic, Health Choice Network, Florida Hospital, WellFlorida and Miami Children’s Health System

- Data Trust IRB Protocol Complete
  Orlando Health, Tallahassee Memorial Health Care, UF Health, Bond Clinic, Health Choice Network, Florida Hospital, WellFlorida and Miami Children’s Health System

- 3 Years of Florida Medicaid Data Migrated into the Data Trust
  AHC, UF Health

- OneFlorida IRB Agreements Complete
  Orlando Health, Tallahassee Memorial Health Care, UF Health, Health Choice Network, Florida Hospital, and Miami Children’s Health System

Next Steps: Statewide IRB training

Research Priorities

10 Million Patients • 4,100 Physician Providers • 1,240 Practices/Clinics • 22 Hospitals • 67 Counties
Current and Upcoming Research Endeavors

**PCORI Health Systems Demonstration Project**
Developing priority topics for data-driven research activities in PCORnet that are of interest to health systems and clinicians

**Heart Health Cross-Cutting Research Group**
Encouraging cross-PCORnet collaborations around heart health

**Pediatrics Cross-Cutting Research Group**
Encouraging cross-PCORnet collaborations around pediatric health

**Cancer Prevention**
Executing several studies through the OneFlorida Cancer Control Alliance

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**PCORI Health Systems Demonstration Project**

In 2015, the PCORI Board of Governors approved up to $5 million in total costs to support engagement and collaboration between leaders of health systems and the health data networks that make up PCORnet. OneFlorida responded to this opportunity with a cross-consortium team to identify three research priorities.
PCORI Health Systems Demonstration Project: Priority Research Topics from OneFlorida

Do patients with co-occurring physical and mental health conditions receive mental health services and recommended care for their chronic physical health conditions?

What is the effectiveness of multi-level interventions aimed at the health care delivery system and the patient and family on reducing potentially preventable inpatient admissions, readmissions, and emergency department visits? Another outcome of interest was improvement in medication adherence post-discharge.

Developing computable phenotypes and predictive algorithms for high risk children related to:
- Metabolic Syndrome
- Neonatal abstinence syndrome (NAS)
- Other conditions

Phase II: PCORI Health Systems Demonstration Project

Release of a limited competition funding announcement for PCORnet networks in early 2016, following the convening of health systems leaders

PCORI will fund up to five, one-year research studies on those priority topics

How can OneFlorida position itself to be competitive for these awards?
PCORI Cross-Cutting Research Groups

Communities of individuals from more than one PCORnet Network organized around a specific issue that impacts health or quality of life for a defined population of individuals. PCORI has launched three initial test pilot groups: Heart Health; Disparities, Vulnerable Populations, and Safety-net Providers; and Pediatrics.

Potential OneFlorida Research Opportunities: Comparative Effectiveness Research • Pragmatic Clinical Trials • Implementation Science Studies

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Heart Health Cross-Cutting Research Group

**STEP 01**
Launch three condition groups, including Hypertension and Congestive Heart Failure, and invite networks to suggest a focus for the third condition group.

**STEP 02**
Convene condition groups, develop list of research teams and study concepts, and vet with patient interest groups.

**STEP 03**
Develop and run a set of preliminary computable phenotypes and core data elements for each condition within each participating CDRN.

**STEP 04**
Present computable phenotype data from participating CDRNs at AHA Epidemiology meeting and invite outside researchers to propose research ideas.

**STEP 05**
Refine research team proposals

OneFlorida Steering Committee Member Rhonda Cooper-DeHoff, Ph.D., will serve as director of the HTN interest group for this CCRG.

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Pediatrics Cross-Cutting Research Group
Creating a OneFlorida Child Health Alliance

- Resources Needed
- Emphasis Areas
- Research Synergies

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Cancer Prevention

- HPV Research
- Tobacco Cessation

Stephanie Staras, Ph.D., received NIH funding to improve and test health information technology in six OneFlorida-affiliated clinics that has helped increase the odds of adolescents starting the HPV vaccine series.

Three studies are about to be launched that examine tobacco cessation in OneFlorida-affiliated clinics and health systems among adults in primary care, pediatric cancer survivors and pediatric oncology patients.
## OUR PROGRESS

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### Researcher Funding Mechanism

<table>
<thead>
<tr>
<th>Researcher</th>
<th>Funding Mechanism</th>
<th>Project Title</th>
<th>Status</th>
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<tbody>
<tr>
<td>Julie Johnson &amp; David Nelson</td>
<td>NIH (U-54)</td>
<td>The OPTIMUM (Optimizing Precision Therapy in Medication USE among Minorities) Transdisciplinary Collaborative Center</td>
<td>Not funded</td>
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<tr>
<td>Folakemi Odedina</td>
<td>American Cancer Society</td>
<td>Validation of a Model of Prostate Cancer Care and Survivorship for Black Men</td>
<td>Not funded</td>
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<tr>
<td>Folakemi Odedina</td>
<td>State of Florida (Bankhead-Coley)</td>
<td>Validation of a Model of Prostate Cancer Care and Survivorship for Black Men</td>
<td>Submitted July 2015, currently under review</td>
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<tr>
<td>Stephanie Staras</td>
<td>NCI (R21)</td>
<td>Maximizing HPV Vaccination: Real-time Reminders, Guidance and Recommendations</td>
<td>Funded</td>
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<tr>
<td>Keith Muller</td>
<td>PCORI (Methods)</td>
<td>Ethical Design and Analysis of Patient-Centered Cluster-Randomized Trials over Time</td>
<td>Submitted Fall 2015</td>
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<td>Carl Pepine</td>
<td>PCORI (Large Pragmatic Trials)</td>
<td>Ischemia-WISE (Will Intensive Strategies Reduce Events in Subjects with Non-Obstructive Coronary Artery Disease (CAD))</td>
<td>Submitted July 2015, will be reviewed January 2016</td>
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<tr>
<td>Rhonda Cooper-DeHoff</td>
<td>UF CTSI (Translational Pilot Program)</td>
<td>Optimizing Antihypertensive Medication in Primary Care</td>
<td>Funded</td>
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<tr>
<td>Chris Harle</td>
<td>AHRQ (R01)</td>
<td>Designing User-Centered Decision Support Tools for Chronic Pain in Primary Care</td>
<td>Received favorable score, anticipating NOA</td>
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2/3/2016
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<th>Researcher</th>
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<th>Status</th>
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<tr>
<td>Diana Wilke</td>
<td>NINR</td>
<td>Optimizing Pain and Respiratory Care for Adolescents and Adults with Sickle Cell Disease in Rural and Urban Northern Florida</td>
<td>Submitted</td>
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<tr>
<td>Gail Keenan</td>
<td>NINR</td>
<td>Applying Big Data Analytics to Standardized Nursing Data: Quality of Palliative Care among Hospitalized Cancer and Cardiac Patients</td>
<td>Submitted</td>
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<tr>
<td>Bob Cook</td>
<td>NIH</td>
<td>Southern HIV Alcohol Research Consortium</td>
<td>Submitted</td>
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Where Can We Partner?

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