QUICK HITS VOL. 3.1 (SUMMER 2018)

ONEFLORIDA NOW SPONSORING 50 RESEARCH PROJECTS

The OneFlorida Clinical Research Consortium has reached another milestone: Consortium researchers have been awarded 50 research projects to date, including four Rapid Research projects funded by PCORI. Among the projects now being conducted using OneFlorida infrastructure and resources:

- **All of Us:** OneFlorida is working with the SouthEast Enrollment Center (SEEC) to recruit 20,000 participants over five years for this NIH program that aims to gather data over time from more than 1 million people across the United States with the goal of accelerating research and improving health.
- **ADAPTABLE:** OneFlorida will enroll 2,200 participants for The Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE) trial, which seeks to determine the ideal dosage of aspirin for patients to prevent heart attacks.
- **Automating Quality and Safety Benchmarking for Children:** Funded by PCORnet and led by PEDSnet director and principal investigator Kathleen Walsh, M.D., at Cincinnati Children's Hospital Medical Center, this project aims to automate quality and safety benchmarking in pediatric care using PEDSnet and OneFlorida, which together have data representing 7.9 million children.
- **PROVIDE-HF:** OneFlorida is participating in the PCORnet study PROVIDE-HF (Patient-Reported Outcomes inVestigation following Initiation of Drug therapy with Entresto [Sacubitril/Valsartan]). The study will evaluate patient-reported outcomes (PROs) for study participants receiving this new medication to treat chronic heart failure compared with PROs for patients receiving the standard ACE-inhibitor enalapril. OneFlorida currently has the third-highest number of enrollees among the six PCORnet CDRNs participating in the study.
- **WARRIOR:** OneFlorida will serve as the recruitment center for the WARRIOR (Women's IschemiA TRial to Reduce Events In Non-ObstRuctive CAD) Trial. Led by OneFlorida researcher Carl Pepine, M.D., the three-year multicenter study funded by the Department of Defense will investigate health outcomes of 4,422 women with non-obstructive coronary artery disease (CAD) across 50 sites.

In addition to these projects, more than a dozen state and national organizations and agencies have provided funding or other support for research involving OneFlorida infrastructure, resources and data, including PCORI and PCORnet, NIMHD, NIH, DOD, AHRQ, Children's Miracle Network, the Florida Center for Brain Tumor Research (FCBTR) and Accelerate Brain Cancer Cure (ABC2), and FACCA.

PROJECT TITLE	PI	FUNDING AGENCY
Characterization of Resistant Hypertension and Associated Outcomes in OneFlorida	Caitrin McDonough	PCORI

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Characterization of Resistant Hypertension Through PCORnet	Caitrin McDonough	PCORI
Vanderbilt-Miami-Meharry Center for Excellence in Precision Medicine & Population Health	Consuelo H Wilkins	NIMHD
Osteonecrosis of the Jaw in OneFlorida Clinical Research Consortium	Yan Gong	NIH
Developing a Facebook app to promote colorectal cancer screening: pilot testing a social media intervention	Yi Guo	CTSI NIH
The Impact of Patient Complexity on Healthcare Utilization	Scott Fields, MD	PCORnet
Identifying and Predicting Patients with Preventable High Utilization	Rainu Kausal	PCORnet
Automating Quality and Safety Benchmarking for Children: Meeting the Needs of Health Systems and Patients	Kathleen Walsh	PCORnet
Hypertension Prevalence and Disparities in the OneFlorida Data Trust	Steven Smith	CTSI NIH

PROJECT TITLE	PI	FUNDING AGENCY
Characterization of the Colorectal Cancer Workup Period Using Network Models Describing Interactions Between Patients and Healthcare Systems	Jiang Bian	
INVESTED: Influenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated Heart Failure	Orly Vardeny	PCORnet
WARRIOR: Women's IschemiA TRial to Reduce Events In Non-ObstRuctive CAD	Carl Pepine	DOD
Aspirin Dosing (ADAPTABLE): A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness	Matthew Roe	PCORnet
Child Health Quality (CHeQ) Partnership Program	Betsy Shenkman	AHRQ
Expanded Access Trial of Systemic Delivery of Aspartoacylase ASPA (rAAV9-CB6-AspA) Gene Vector in a Single Patient with Canavan Disease	Barry J. Byrne	Internal
Development of a Computable Phenotype for Duchenne Muscular	Rebecca Willcocks	Internal
All of us	Stephan Zuchner	NIH

PROJECT TITLE	PI	FUNDING AGENCY
PROVIDE-HF Patient Reported Outcomes inVestigation following Initiation of Drug therapy with valsartan/sacubitril in Heart Failure	Robert Mentz	Industry – Novartis
The UF Catchment Area Linkage Project: Pilot Testing an Encrypted Hashing Algorithm Methodology	Elizabeth Shenkman	Internal
Validation of a computable phenotype for juvenile idiopathic arthritis	Natalie Jane Shiff	Children's Miracle Network
Risk Factors associated with an increased incidence of patient safety events following resection of glioma	Dimitri Laurent	
Real World Survival Data for Glioblastoma patients using the OneFlorida database	Ashley Ghiaseddin	Florida Center for Brain Tumor Research (FCBTR) and Accelerate Brain Cancer Cure (ABC2)
Identification of Microbiome Profile Alterations in Fecal samples from Children with Recurrent Abdominal Pain	Devendra Mehta	FSU Seed Grant (CTSA)
Developing a Facebook app-based social media intervention to increase colorectal cancer screening among Hispanics.	Yi Guo	NIH

PROJECT TITLE	PI	FUNDING AGENCY
Pathways to Early Parkinson's Disease Diagnosis from the Emergency Department	Adolfo Ramirez-Zamora	Internal
Developing a Precision Population Health Intervention for Hepatocellular carcinoma Screening	Betsy Shenkman	Internal
Rapid Research: Trends and current prevalence of PCSK9 inhibitors	Rhonda Cooper-Dehoff	PCORnet
Florida increases rates of screening and treatment of hepatitis C virus (FIRST HCV)	Anna Giuliano	FACCA
Development and Validation of a Computable Phenotype for Type 1 Diabetes	Desmond Schatz	PCORnet
Rapid Research: Molecular Diagnosis and Targeted Therapy in Cancer	Elizabeth Chrischilles	PCORnet
OneFlorida: Trends in Hydroxyurea Utilization for the Treatment of Sickle Cell Anemia in Children, Adolescents, and Young Adults in Florida	Vandy Black	Internal

PROJECT TITLE	PI	FUNDING AGENCY
Tailoring HPV Vaccination Intervention Strategies to Local Area Needs	Stephanie Staras	CPS Collaborative Team Grant Budget
Evaluation of the role of cholesterol in diseases of impaired myelin function in the state of Florida and the evaluation of treatment disparities.	James Wymer	Foundation
Delineation of ALS Treatment Disparities and Barriers to Healthcare in the state of Florida	James Wymer	Internal
Safety of Direct-Acting Antivirals for Hepatitis C	Elizabeth McGlynn	PCORI
Rapid Research: Diabetes Incidence Prevalence and Medications Use	Russell Rothman	PCORnet

ONEFLORIDA PORTFOLIO PROGRAM AWARDS MOC CREDIT TO FIRST GROUP OF PHYSICIANS

OneFlorida has begun its first Portfolio Program research project to tie Maintenance of Certification (MOC) credit to study participation.

ONEFLORIDA RESEARCH TEAM WINS AMIA DISTINGUISHED PAPER AWARD

A paper co-authored by a team of OneFlorida researchers was selected for the American Medical Informatics Association's (AMIA) 2017 Distinguished Paper Award at AMIA's 2017 Annual Symposium in Washington, D.C. in November.

QUICK TIPS

SIRB TIPS

By Jane-Ann Norton
Beginning January 28, 2018, the National Institutes of Health (NIH) began mandating the use of a Single Institutional Review Board of Record (sIRB) for NIH-funded multi-site research studies involving human subjects. How will this new regulation affect OneFlorida researchers?

OneFlorida will continue to offer its current central IRB model for consortium partners conducting multi-site human subjects research within the consortium. The University of Florida (UF) IRB serves as the central IRB for OneFlorida studies.

For OneFlorida researchers whose multi-site studies include institutions outside of the consortium, the principal investigator of the study must either designate the UF IRB as the study's sIRB or cede UF IRB oversight to another IRB at one of the other participating institutions.

Either way, investigators must *contact the IRB as early as possible in the study design process*. There are significant differences, responsibilities, and potential costs to you for conducting research via an sIRB. Moreover, OneFlorida investigators who opt to cede UF IRB oversight to another IRB still must involve the UF IRB in the sIRB review.
Requests for a UF IRB to Serve as the sIRB: Contact the IRB Office (352-273-9600) early on in your grant preparation to determine if a UF IRB can provide this service, and what costs should be included in your grant. The same process should be followed irrespective of the funding source.

Ceded Study Reviews: Every agreement with other institutions (including the SmartIRB Reliance Platform) requires UF to perform certain duties, such as assessing payment language, conflict of interest, training completion, protection of vulnerable subjects, state law, privacy/HIPAA, HURRC, etc. The UF IRB requires all ceded study reviews to be entered into myIRB as an abbreviated application. Completing all the required reviews takes time. Please plan accordingly.