

# University of Florida

## College of Medicine-Jacksonville

### Research Overview

Alan R. Berger, M.D.  
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Professor and Chair, Neurology  
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Office of Research Affairs, Division of Sponsored Research

# Overview

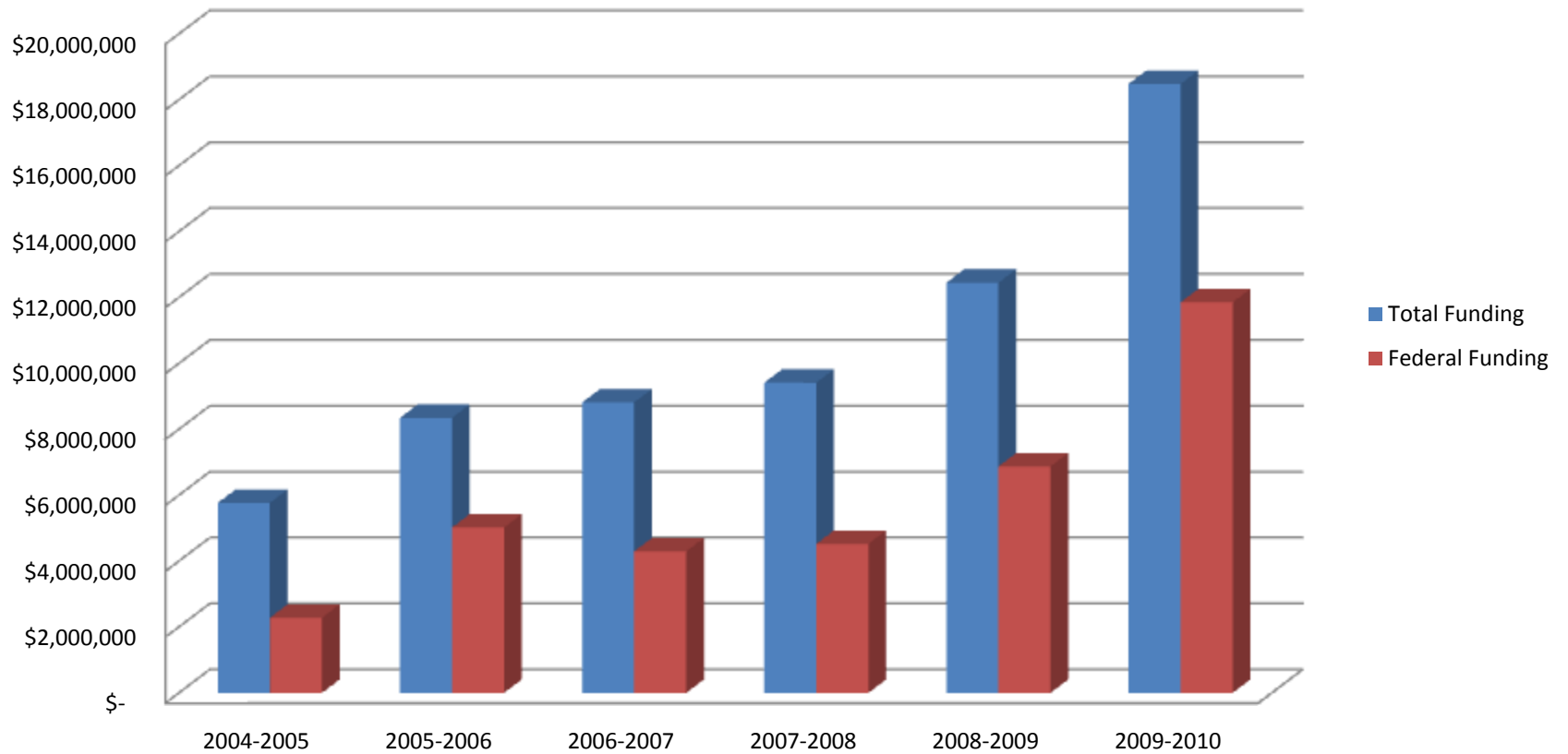
- 225 funded projects in 09/10. Research funding \$18.48 million in 09/10 (\$11.85M -64% of research is federally sponsored projects). Increase of 48% in research funding over last year, increase of 72% in federal funding over last year.
- The research funding for the 6 months of this FY (10-11) is \$12.1 million . This is an increase of 7 % over the same period last FY. As of today, the research funding is \$13.2 million.
- Increase in external funding by 220% over the last five years. Over 420% increase in federal sponsored funding over the last five years.
- Increase in proposal submission by 15% over last year, increase to federal sponsors by 20%.

# COM-Jacksonville Research Funding

**Fiscal Year 2009- 2010**

<b>Federal</b>	<b>\$</b>	<b>11,852,586</b>
<b>Industry</b>	<b>\$</b>	<b>2,524,704</b>
<b>Foundation/Society</b>	<b>\$</b>	<b>794,199</b>
<b>FL State Agencies</b>	<b>\$</b>	<b>3,309,074</b>
<b>Total</b>	<b>\$</b>	<b>18,480,563</b>

# COM-J Federal Funding Growth



# Research Support

- **Office of Research Affairs (ORA)**

ORA is a full-service research support office providing assistance and training for all aspects of the research enterprise to researchers on the UF regional campus in Jacksonville.

# What ORA Does

- Disseminates research policy and procedure information (e.g., the research manual)
- Hosts monthly meetings & teleconferences for research support staff
- Administers the Dean's Fund and other internal grant programs
- Organizes the annual Research Day
- Oversees Jacksonville campus research space
- Maintains the clinical trial website

<http://www.hscj.ufl.edu/medicine/research-affairs/search/>

# What ORA Does

- **Pre-Award**
  - Provides funding opportunity information
  - Approves & submits government & private agency research proposals
  - Reviews & negotiates non-disclosure & clinical trial agreements
  - Provides assistance & training for preparing:
    - Budgets
    - Sponsor documentation
  - Assists with budget negotiations & other interactions with pharmaceutical sponsors
  - Signs all agreements, proposal submissions, and award acceptances as official institutional signature authority for all research on the Jacksonville regional campus

# What ORA Does

- **Post-Award**
  - Sets up research project accounts in conjunction with Award Administration (Gainesville)
  - Distributes Notices of Awards (NOAs)
  - Negotiates & executes subcontracts & agreement amendments
  - Facilitate with UF Contracts & Grants and DSR Awards offices in Gainesville on behalf of Jax campus researchers
  - Provides training for:
    - Entering project & budget information into the UF PeopleSoft system
    - Accessing account balances and monthly financial reports
    - Assist PI/Departments with disbursements including:
      - Processing invoices
      - Generating purchase orders
    - Assist with closing out research projects & accounts



# Jacksonville Institutional Review Board

## IRB-03

an IRB is an appropriately constituted group that has been formally designated to **review and monitor research involving human subjects**. An IRB has the **authority to approve, require modifications in** (to secure approval), **or disapprove research**. This group review serves an important **role in the protection** of the **rights and welfare of human research subjects**.

# IRB Overview

- Over 550 active clinical research studies performed by COM-J faculty, fellows and residents
- IRB-03 have continually increased productivity (more federal sponsored, non-pharma sponsored & investigator initiated research). WIRB volumes decreasing (less pharma sponsored clinical trials). IRB-03 electronic submission and review has increased efficiency and approval process .
- Continued increase in the numbers of faculty conducting research on campus.
- Click Commerce -1) standardize IRB submission; 2) provide 24x7 status information regarding IRB submissions; 3) simplify IRB submissions by supporting reuse of IRB materials; 4) improve turn around time by reducing the number of tabled protocols. Jacksonville implementation in Phase 2 (Late summer/Fall 2010). Integration with CTSI undertakings.

# Clinical Research COM-Jax

- Clinical Research Unit (CRU) at Shands Jacksonville is a dedicated research unit to perform inpatient studies with a research coordinator manager and full time clinical bedside nursing care. Research coordinator services and administrative assistance for outpatient studies for division/dept without sufficient research coordinator staff.
- The CRU is part of the CTSI initiatives on this campus.
- Strong clinical programs for successful recruitment and retention
- Strong ties with industry and pharmaceutical companies facilitate participation in multi-centered pharmaceutical and device trials grants both federal and industry sponsored.

# Other Notable Research Programs

- National Children's Study Site for Baker County under a grant from NIH to University of Miami
- NIH-funded programs in health safety, healthcare technology and diagnostics advances
- NIH- funded Diabetic Retinopathy Clinical Research Network
- NIH-funded Insulin resistance intervention after stroke; Local Identification and Outreach Networks (LIONS) for Stroke Trial Recruitment
- Medical Simulation Research Programs

# University of Florida Center for HIV/AIDS Research, Education and Service (UF CARES)

- Community engagement with
  - Targeted Outreach to Pregnant Women with AIDS (TOPWA): CDC funded
  - African American HIV Testing Initiative (ATTI): CDC funded
  - HIV education and training for north Florida and panhandle (over 800 hours of training activity this academic year): HRSA funded
  - HIV Community Care Network: Consortium of community based HIV service organizations

# COM-J Research Boards

- Research Advisory Council is designed to provide direction to the dean, and provide oversight to the research mission, and opine as to the direction and degree of research resources for the campus
- Academic Achievement Council is designed to increase scholarly activity and research productivity of the current faculty

# Clinical and Translational Science Institute

## How did we get here?

- In July of 2009, UF received a \$26 million NIH Clinical Translational Science Awards, establishing the UF CTSI.
  - The UF Office of Research provided additional \$23 million in support
  - The UF College of Medicine has made \$70 million in commitments
  - 12 Colleges → 20% effort for members, faculty lines, space, equipment
- The result: an institute dedicated to enhancing human health by accelerating the translation of basic research into new clinical treatments as quickly as possible.

# Philosophy of the UF CTSI

## University of Florida Colleges

Agricultural and Life Sciences, Dentistry, Engineering, Fine Arts, Health and Human Performance, Journalism and Communications, Business, Liberal Arts and Sciences, Medicine, Nursing, Pharmacy, Public Health and Health Professions and Veterinary Medicine  
(Gainesville and Jacksonville campuses)

Clinical and Translational  
Science Institute

Community  
IFAS Extension  
Partnerships-FSU

Healthcare Systems  
Shands –GA/Jax  
N. FL/S. GA VA  
Orlando-Lake Nona



# Clinical Translational Science Institute (CTSI) <https://www.ctsi.ufl.edu/>

- Access to CTSI portal-focal point for collaboration, integration and research support across the program activities of the CTSI
- Creation of many registries- study registry, investigator registry, data registry
- Expand informatics support for investigators
- Community engagement and research collaborations
- Participation in courses, seminar series, presentations

# What the UF CTSI Provides

- Current services provided:
  - Clinical Research Units
  - Research Support
  - Laboratory Services
  - Funding Opportunities
  - Training Opportunities

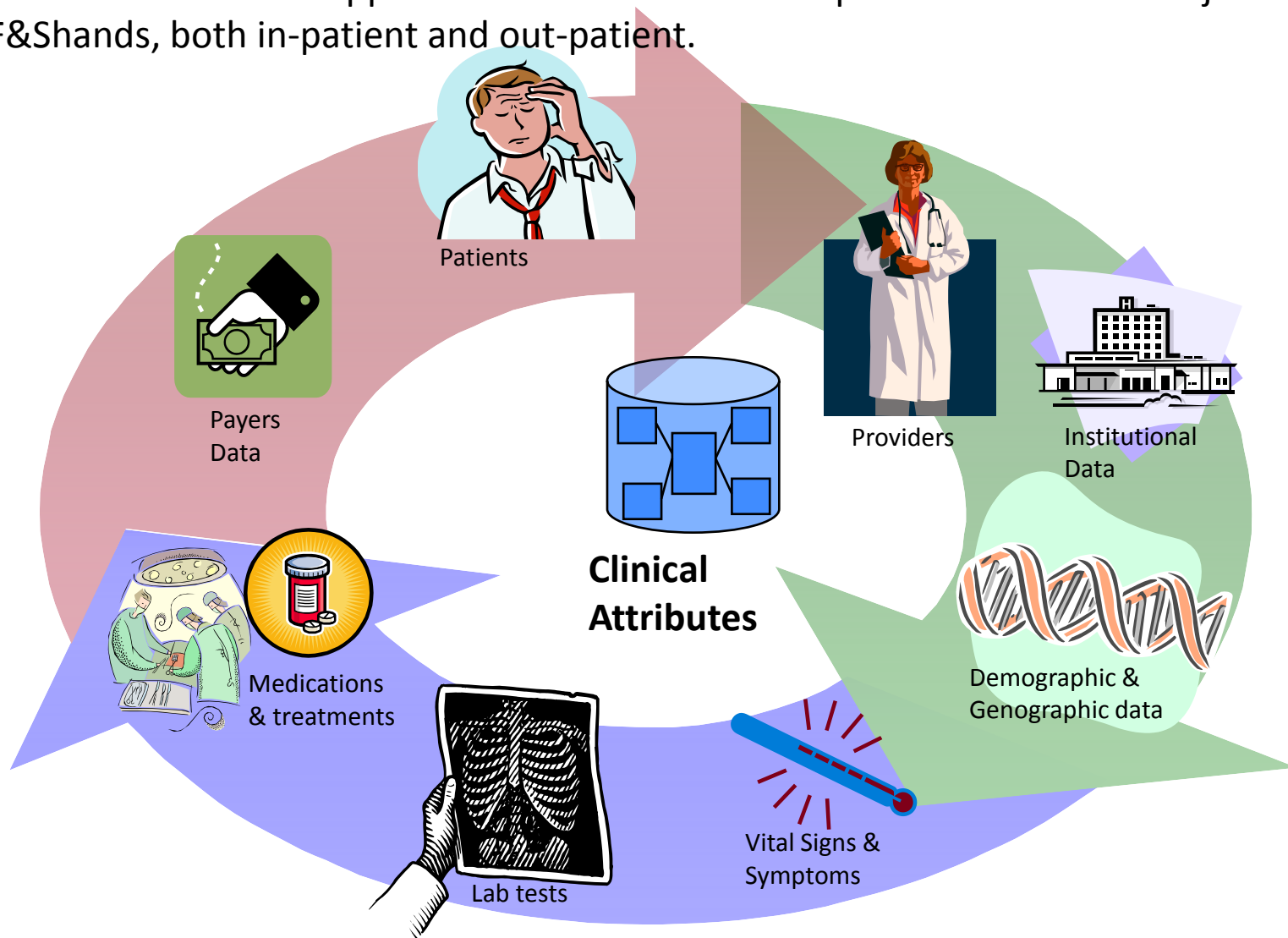
# Improving Clinical Trials Infrastructure

## Ongoing Projects

- Consent for research use of tissue and data
- Clinical faculty research initiative
- Click commerce for IRB implementation
- Integrated data repository
- Billing and budget tool
- Clinical trial listing
- Clinical and Translational Research Building (CTRB)

# Integrated Data Repository (IDR)

Goal: Development and implementation of a UF Academic Health Center that will house data generated and integrated from the clinical enterprise, clinical trials, and basic research mission. The IDR will support cohort identification of potential research subjects at UF&Shands, both in-patient and out-patient.



# Community Engagement Activities

- CRA in Jacksonville is currently involved in four initiatives:
- The UF & Wolfson Children's Hospital Community Based Pediatric Research Network – Director : Mobeen Rathore
- Health Risk Assessment in Children and Adolescent – PI: Betsy Shenkman, PhD
- Concussion Surveillance/Management in children and Adolescent – PI: Russ Bauer, PhD
- Coordination of Community Advisory Board for the CERP of the CTSI – Shenkman and Rathore

# How CTSI can help Jax faculty

- Project management: investigator initiated question/project- assistance with design, collaborators, core facilities
- Funding and training opportunities: intramural funding (2-4 RFA/yr), KL2 scholar support, community engagement projects (CRA support)
- Red Cap database: secure, web based platform provides streamlined process for developing databases; branching logic, calculated fields and automated date validation
- Seminars, lecture series and webcast capabilities
- Integrated Data Repository(IDR): support cohort identification of potential research subjects at UF&Shands, inpatient and outpatient
- CRU: Shands Jacksonville inpatient unit/outpatient services
- Community engagement activities/network: Jax based CRA

# Basic Science/Translational Science Activities

- Department of Medicine
- Department of Anesthesiology
- Department of Ophthalmology
- Department of Radiology
- Department of Surgery
  
- Currently over 16,000 sq. ft. research space, including 12,000 sq. ft. facility for basic science/translational research.

# Michael Haas, PhD/ Arshag Mooradian, MD

- characterizing molecular mechanisms that regulate expression of one of the key components of HDL, its constituent protein apolipoprotein A-I (apo A-I).
- examining the relationship of vitamin D and plasma HDL



# Minghui Xiang, Ph.D

- investigating roles of novel sodium hydrogen antiporters (NHA) in hypertension and diabetes,
- Role of NHA1 and NHA2 in essential hypertension
- Role of NHA1 and NHA2 in diabetes
- **Xiang (PI)** NIH/NIDDK (R21); Role of the Novel Na<sup>+</sup>/H<sup>+</sup> Antiporter NHA2 in Diabetic Kidney Disease

# Charles Heilig, MD

- investigates the roles of glucose transporters in the development of disease focus primarily on the roles of glucose transporters in kidney disease, particularly diabetic kidney disease.
- also investigates glucose transporter involvement in nondiabetic kidney disease, diabetic embryopathy and the glucose transporter deficiency syndrome.
- Dr. Heilig patented his continuous lines of rat mesangial cells with altered GLUT1 expression as an in vitro model for the testing of new drugs to prevent diabetic glomerulosclerosis (U.S. Pat. #5,939,275). This in vitro model has been used to identify a promising class of anthraquinone drugs to prevent diabetic kidney disease.

# Charles Heilig, MD

- also developed transgenic mice with overexpression of GLUT1 in kidney mesangial cells to mimic the increased glomerular GLUT1 in diabetic animals.
- **Heilig(PI)** *JDRF Innovative Grant Award ; Novel Role for MGF in Development of Glomerulosclerosis*

# Xiaoyu Li, MD, PhD

- research has been focused on hepatitis C virus (HCV): interactions of human innate immunity and hepatitis C Viral (HCV) replication to develop better therapeutic agents or strategies for treatment of HCV.
- focused on the biological activities of IFNs including activation the Jak/Signal Transducers and Activator of Transcriptions (STATs) pathway and expression of a large number of interferon-stimulated genes (ISGs) which are normally quiescent or expressed at low level.

**Li (PI)** NIH-NIDDK (K08); Mechanistic Studies of Hepatitis C Viral Translation

**Li (PI)** Florida Department of Health: Bankhead New Investigator Grant; Screening of Chemicals to Enhance Interferon Effects as Therapeutic Agents

# Dominick Angiolillo, MD, PhD

- Thrombosis Research Center (TRC)-conduct seminal investigations on describing and understanding mechanisms involved in variability in individual response to antiplatelet therapy.
- conduct pilot investigations to define strategies of individualizing treatment in high risk patients.
- TRC has accumulated among the largest experience world-wide for testing antiplatelet agents under clinical investigation as well as conducted experiments which have served for the FDA to give approval for devices as well as update to package inserts of antiplatelet medications

# Christopher Williams, MD/Marie Becker, PhD

- Current projects include investigation of novel combinatorial molecular therapies in bladder cancer
- Efforts are underway to genetically silence GSK3 $\beta$  in order to assess the effect on cell proliferation, colony formation and migration.
- An additional project in the lab targets another pathway, the mTOR pathway. the process of exploring novel dual mTORc1 and mTORc2 inhibitors for their effectiveness in reducing cell proliferation in bladder cancer cell lines.
- Ongoing IRB-approved tissue bank to store small samples of surgical specimens to be used for research.

# Christopher Williams, MD/Marie Becker, PhD

- 2010 Recipient of the University of Florida and Shands Cancer Center, American Cancer Society Chris DiMarco Institutional Research Grant Junior Investigator Award
- **Williams (PI)** James and Esther King Florida Biomedical Research Program New Investigator Award; *GSK3-beta: a novel molecular therapeutic target in human bladder cancer*

# Joana Panni, PhD/Moeen Panni, MD

- Laboratory research interest focused on the investigation of the effects of anesthetic medications on neural function using chick embryo or chick ALS-type models (a Lou Gehrig disease model).
- Assess the potential effects of different anesthetic agents on tumor progression, vascularization and metastasis in a chick animal model of nervous system tumors, such as glioblastomas and neuroblastomas.



# KV Chalam, MD/Ophthalmology Department

- *Evaluation of Role of Stem cell based therapy in reversal of diabetic retinopathy*-collaborate with Dr. Maria Grant, Professor of Pharmacology and Therapeutics in elucidating the role of transformed bone marrow derived stem cells in prevention as well as reversal of diabetic retinopathy. NIH R01 to carry out this translational research

# KV Chalam, MD, PhD/Ophthalmology Department

- *Implications of anti-VEGF therapy on ocular physiology and pathobiology.*
- *Safety of use of various dyes in ocular surgery.*
- *Effect of pathological ocular environment on ocular tissue.*
- *Effect of Proton beam radiation on ocular tissue.*

# Radiology Department

- Faculty working with **UFPTI** on lung carcinomas using PET/CT and to determine the effectiveness of MRI in the staging and diagnosis of prostate cancer.
- investigating the simultaneous acquisition of calcium scoring, coronary angiogram, and perfused blood volume in the myocardium during cardiac CT exams
- evaluate the relationship between RV dysfunction and PA compliance in PAH using 3T MRI imaging
- On going collaborations with Siemens

# Medical Research Program in Medicine

- Residents encourage to participate in research on orientation day, advised to seek faculty mentors
- Series of lectures focused on clinical design and statistics as well as basic molecular biology, genomics and proteomic techniques.
- Yr 2 and 3- one month of research electives to participate in various approved research projects
- Sub-specialty residents also participate substantially in basic, clinical, and translational science research. Basic science training starts with the basic safety associated with the use of chemicals and biohazardous substances, as well as the safe use of radionuclides, UF, state, and federal policies regarding these issues.

# CHEQR

Center for Health Equity and Quality Research

Director: David Wood, MD, MPH

Co-Director: William Livingood, PhD

# Vision, Mission, Goals

- Be a national leader in the study of on HEALTH DISPARITIES experienced by African American and poor populations
- Conduct CBPR, intervention and QI research to reduce health disparities in NE Florida
- Collect data across the UF&Shands health care enterprise and population served to inform the development of programs
- Improve the quality of care across outpatient/ED/inpatient services in critical clinical conditions that impact our populations of focus
  - Diabetes, Stroke, Cancer, Sickle Cell Disease, HTN, CVD

# Who we are:

- Director: David Wood, MD, MPH
- Co-Director: William Livingood, PhD
- Research Administrator: Katryne Lukens Bull, MPH
- PBRN Project Director: Joyce Balls-Berry, PhD
- Statistician: Ryan Butterfield, DrPH©
- Statistician: Carmen Masnita Iusan, MS
- Research Assistant: Mark Fafard, BA
- Hiring:
  - PhD Statistician; Dale Kraemer, PhD, early Summer
  - PhD Mental Health Researcher---SAMHSA Project funded
  - MS/MPH—SAMHSA Project funded

# Faculty/Areas of work

- Jacksonville
  - Adult cancer—Volpe, Samiian
    - Breast health disparities
    - GI Cancer
  - Stroke—Silliman, Sanders
  - Diabetes—Alexandraki, Edwards, Palacio, Mooradian
  - Child Mental Health—Goldhagen, Cuffe
  - Child Development—Childers
  - Palliative Care—McIntosh
  - Transition readiness—Wood, Edwards, Livingood
  - Hispanic Health—Beverly, Solo-Josephson
  - 22 Residents/fellows: Peds ED, OB/Gyn, Neurology, Orthopedics, Pediatrics, Peds ID, Pharmacy, Gastroenterology, Internal Medicine, etc
- Gainesville
  - Cancer Survivorship—Shearer (Gainesville)
  - Medical Home/Health Disparities—Hall (Gainesville)





# CHEQR Benchmarks 2011

- Grants
  - Submitted 14 grant proposals
  - 2011 Awards: \$573,700.00
    - SAMHSA evaluation
    - Aetna Grant, Allyson Hall (PHHP), PI
  - 5 pending applications
- Scholarship
  - 14 Publications
  - 13 faculty members
  - 9 abstracts to National Conferences

# CHEQR & the JaxHERO PBRN

- Jacksonville Health Equity Research Organization
  - 28 UF&Shands Clinics—FM, IM
  - 120,000+ patients; huge reach across Jacksonville
  - Measure and Reduce Health Disparities across UF&Shands
- Reducing Diabetes-related health disparities
  - 12,500 patients with type 2 diabetes in the UF&Shands system
  - A minority are making goals for control: BP, HbA1c, LDL
  - Grant to pilot test Medical Home & Peer Patient Navigator (community) intervention to improve processes and outcomes of care

