The Clinical and Translational Science Institute

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Jacksonville, Florida
May 16, 2013
National Institutes of Health
Clinical and Translational Science Awards

• In 2006, NIH developed the Clinical and Translational Science Award (CTSA) Program
• The CTSA consortium vision:
  • to improve human health by transforming the research and training environment to enhance the efficacy and quality of clinical and translational research
• National Strategic Goals:
  • National Clinical and Translational Research Capacity
  • T1 Translational Research
  • The Training and Career Development of Clinical and Translational Scientists
  • Consortium-Wide Collaborations
  • The Health of our Communities and Nation
• The 61 CTSA institutions are linked together to transform the local, regional, and national environment to increase the efficiency and speed of clinical and translational research

The UF CTSI is supported in part by NIH awards UL1 TR000064, KL2 TR000065 and TL1 TR000066
Clinical and Translational Science Award Consortium

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The Four Translations

T4 – Translation to population health. Studies outside care settings. E.g. Weight loss, access to care, behavioral studies.


T2 – Translation to patients. Demonstrate use is safe and effective. E.g. Clinical Trials.

T1 – Translation to humans. Scientific discoveries applied to human health. E.g. Genetics, engineering.
Concept Organization

Transformation

- Develop new capabilities for research and translation to practice

- Community Engagement. Includes HealthStreet. Jacksonville, Lake Nona. U Miami collaboration

- Personalized Medicine. Includes Pharmacogenomics

- Communications Research

- Clinical Research. Includes recruitment and retention, information support, venues, PBPRNs, research efficiencies

- Implementation Science. Includes Patient-centered outcomes research support, project-based translation to practice

- Florida State University. College of Medicine, state-wide physician network, National High Magnetics Field Laboratory, Health Impacts

- Southeast Center for Integrated Metabolomics. Includes global and targeted metabolomics, Sanford-Burnham collaboration

Service

- Provide state-of-the-art, effective and efficient services and resources for research

- CTSI Service Center
  - Services and resources for investigators. Metrics, program income model, cost recovery
  - Navigators
  - Informatics
  - Biostatistics
  - Regulatory
  - REDCap
  - Laboratories
  - Biorespository
  - Ethics
  - IRB Support
  - Grant Writing
  - IDR
  - 50 additional services
  - Referrals to university services — ICBR, Library, HPC, Survey Center

Education

- Develop the next generation clinical and translational workforce

- CTSI Education Programs
  - Formal and informal training, education and development for the CTS workforce
  - KL2
  - TL1
  - APPCI
  - MS CTS
  - Academy of Research Excellence
  - Research Coordinator Training
  - Referrals to university programs — Howard Hughes, MD-PH.D, CPET, CERHB, Jr. Honors Medical Program, AHC Training

CTSI Home

- Strategic Planning, External Advisory Board, Internal Advisory Board, Leadership Group,
  - Program Support, Finance, Communications, Evaluation
  - Seminar Series, Pilot and Voucher Support
Services and Resources

- Biostatistics
- Education Programs
- Population Science
- Laboratory Science
- Clinical Science
- Funding Programs
- Informatics
- Data Services
- And More

In 2012, more than 900 UF investigators received services from the CTSI. Note: Many services are provided at no-cost to investigators. Other services have charges associated. Please contact service providers regarding their charges, if any.
Research Design and Analysis

• Overarching goal
  – Consult, collaborate, conduct research, and educate on study design and biostatistical issues in CTS

• Activities
  – Study Design – clinical trials, observational studies, cohort, chart review, qualitative, epidemiologic
  – Power Analysis
  – Data Analysis
  – Data presentation and visualization
  – Qualitative research collaborations
  – Survey design
  – Data Coordinating Center Services
  – Study Design Lunch Series

Jon Shuster, PhD
Translational Technologies and Resources Program

• Overarching Goal
  – Develop and Provide basic science tools and services for research

• Services
  – CTSI Biorepository (M. Clare-Salzer)
  – Genotyping (J. Johnson)
  – Biobehavioral (S. Nixon)
  – Human Imaging (S. Lai)
  – Biomedical Mass Spectrometry (T. Garrett)
  – Global Metabolomics (D. Powell)
  – Quality Assurance, GCP, GLP (C. Abernathy)
  – Simulation (S. Lampotang)

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CTSI Biorepository

- Biospecimen collection, processing and storage. Stored biospecimens can be used by any researcher with IRB-approved protocols.
- Prospective biospecimen collection to fulfill investigator needs for IRB-approved protocols.
- Storage for biospecimens collected by investigators. Stored biospecimens belong solely to the investigator.
- Oversight of the release of biospecimens from the UF Department of Pathology for other IRB-approved research protocols.
- Pathology services including those provided by the Molecular Pathology Core and confirmation of diagnosis by a board-certified pathologist upon request.

One of two Hamilton Storage Technologies’ SAM -80°C automated sample management systems (Robotic freezers). The biorepository also has eight Forma Thermo Scientific -80°C Freezers with back-up CO₂ and sensaphone alarm systems including back-up storage space, centrifuge for basic bodily fluid processing, QiaCube for small volume RNA, DNA and protein purification, Agilent Bioanalyzer for RNA, DNA and protein quality control analysis, OnCore BioSpecimen Management.

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Human Imaging Core

- Structural and functional MRI
- Methods and protocols for MRI data acquisition
- Image quality assurance and quality control
- Image acquisition and transfer support
- Image archive, review, and access
- Teaching investigators data acquisition and analysis techniques
- Assisting researchers in designing experimental protocols
- Development of advanced MR imaging and spectroscopy methodology

The centerpiece of the Core is a state-of-the-art 3.0 Tesla, 32-channel Philips whole-body human MRI scanner dedicated to research. The scanner is equipped with a series of coils for imaging human organ systems, including a 32-channel head coil for neuroimaging applications with significant gains in signal-to-noise ratio and acquisition speed. An ESys® system by Invivo is available for presenting video and audio signals including functional MRI task paradigms to the subjects during scanning.

The UF CTSI is supported in part by NIH awards UL1 RR029890, KL2 RR029888 and TL1 RR029889.
CTSI REDCap Services

- No-charge, unlimited self-service access to REDCap and REDCap Survey
- Training in REDCap data entry and study set-up
- Support Services
- Configuration Service

Participation in the national consortium

- Augmented REDCap to use standard sign-on methods (GatorLink)

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Informatics

• Clinical and Translational Science IT (Felix Liu, PhD)
  – Software development
  – Web site design
  – Database design
  – Equipment interfaces
  – Hosting and application support (60 systems including REDCap, Health IMPACTS, CTSI Portal, Personalized Medicine, Study Registry, investigator systems)

• Collaborate with
  – Academic Health Center IT (Kari Cassel)
  – Integrated Data Repository (Gigi Lipori)
  – UF Research Computing (Paul Avery, Erik Deumens)
  – Investigative groups across UF and beyond

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Clinical Research Program

Overarching goal

• Create new opportunities for clinical research

Clinical Research Units

• Locations: Gainesville (UF and VA), Jacksonville, Orlando

• Disease expertise: Aging, Cancer, Cardiovascular, Dental, GI/Hepatobiliary, Neuromedicine, Pain and Sensory Testing, Sleep Disorders, Tuberculosis and Emerging Pathogens

• UF Clinical Research Center moving to the CTRB in June 2013
Pilot Projects Program

• Overarching Goal
  – Support emerging research via institution-wide competitive funding for CTS, targeting trainees, junior faculty; methods (IP) development; and multi-discipline, trans-college initiatives.

• Activities
  – Two annual general RFAs, 36 awards, $530K in 2012
  – Service vouchers
  – CTSI Seminar Series
  – Design Series

Chris Batich, PhD

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Integrated Data Repository

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Academy of Research Excellence

Launched in 2012 as part of UF’s continuing commitment to excellence in health science research, the CTSI Academy of Research Excellence will help promote high-quality, innovative clinical research, with the highest regard for research integrity, ethics, professionalism and regulatory requirements.

The academy is dedicated to promoting an atmosphere of professional collegiality and openness, including active role-modeling and the mentoring of junior faculty and health science students.

Inaugural members of the CTSI Academy of Research Excellence include (bottom row, left to right): Peggy Borum, Emina Huang, Jacqueline Hobbs, Latha Stead, Gary Wang, Katherine Karpinia. (Top row, left to right): Michael Bubb, Reginald Frye, Thomas George, David Winchester, Samsun Lampotang, Todd Manini, Barbara Lutz and Ramon Rodriguez.
CTSI Education Programs

• Overarching Goal
  – Train a new generation of multi-disciplinary CTS researchers and leaders in academia, industry and government

• Programs
  – KL2 Multidisciplinary Program for Junior Faculty
  – TL1 Pre-doctoral training program
  – Advanced Postgraduate Program in Clinical Investigation
  – Research Coordinator Training
  – Masters in CTS
  – Academy of Research Excellence

• Affiliated Programs
  – Junior Honors Medical Program
  – Center for Precollegiate Education and Training
  – Center of Excellence for Regenerative Health Biotechnology
  – MD-PhD
  – HHMI Science for Life
  – Health Science Center Training
  – Interdisciplinary Program in Biomedical Sciences

Marian Limacher, MD

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Community Engagement and Research

Overarching Goal
To promote collaborative relationships with communities to address the health and well-being of community members

Resources
- Community Advisory Boards
- Community Research Associates
- HealthStreet
- Health Impacts
- Research Networks

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**Assessment:** Assess health issues and concerns from community residents

**Education:** Provide informational materials and resources tailored to health promotion, wellness and dissemination of new research knowledge for community stakeholders

**Service:** Link individuals who have been underrepresented in services and research to social services, health care and research opportunities

**Communication:** The HealthStreet site will serve as an anchor for community groups and investigators to engage in bidirectional, health-focused communications with the goal of increasing community engaged research partnerships

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Personalized Medicine Program

• Background
  – Human genome project completed in 2001
  – Collins (NIH): expectation that an individual’s personal genome will be part of their medical record, from which information can be pulled to determine disease risk or guide treatment decisions

• Challenge
  – Despite the substantial number of important genetic discoveries made, there are limited examples of clinical translation to practice

• UF Objectives for Personalized Medicine Program
  – Position UF&Shands Health System as leaders in genetic-guided care
  – Pre-emptively genotype on broad panel (256 SNPs) to mimic eventual reality of genomic data in EMR
  – Prepare health informatics systems to handle increasing amounts of genetic data linked into EMR
  – Define when and how to use genetic data in patient care
Challenge: genetic polymorphism of CYP2C19 leads to reduced ability to activate clopidogrel (Plavix) and increased risk of cardiovascular complication.

Personalized Medicine Information Flow

- Challenge: genetic polymorphism of CYP2C19 leads to reduced ability to activate clopidogrel (Plavix) and increased risk of cardiovascular complication.

- CER, Economic Impact
- Research and clinical consent; Bioethics; Communications Research
- BMI; Hospital IT; Epic
- Biorepository
- Genotyping Core
- IDR; Bioinformatics; Research IT

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Personalized Medicine Program-Launched June 25, 2012

UF delvers promise of personalized medicine to heart patients

Personalized medicine — a concept in which an understanding of a patient’s genetic makeup is used to enhance treatment — has arrived at UF&Shands, the University of Florida Academic Health [...]

https://ufandshand.org/news/2012/uf-delivers-promise-personalized-medicine-heart-patients#l/-1/
**Goals**

- Test interventions in physician practices;
- Translate research findings into improved health care quality; and
- Mentor medical students and trainees in conducting research and implementing research findings in practice.

**Two pilot projects**

- Sports related concussion surveillance and management (PI: Bauer)
- Health risk assessment among adolescents in primary care (PI: Shenkman)

**Funding**

- UF/FSU ($500,000)
- State of Florida ($600,000)
- NIH ($473,000)
UF-Affiliated Research Networks

• **Local/ Regional**
  – North Florida Pediatric Community Research Network (Jacksonville area)
  – Jacksonville Health Equity Research Organization Practice-Based Research Network (JaxHERO)

• **Statewide**
  – Health IMPACTS for Florida (UF-FSU statewide research network)
  – Florida Neonatal Neurologic Network

• **National**
  – NHLBI Cardiovascular Cell Therapy Research Network (Carl Pepine)
  – NIDCR Dental Practice-Based Research Network (Valeria Gordan)
  – Hepatitis C Therapeutic Registry and Research Network (David Nelson)
  – Network for Pancreatic Organ Donors with Diabetes (Mark Atkinson)
  – NIH Pharmacogenomics Research Network (Julie Johnson)
  – Sentinel Network for Community-Based Participatory Research (Linda Cottler)

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Consent2Share

- Initiated on 9/11/12
- Consent form given with admissions packet (pt. specific bar code)
- Consent asks 2 questions
  - Can we store your excess tissue with protected health information?
  - Can we re-contact you for a future study?
- Collected by admissions clerk, data entered into EPIC, consent form scanned with other documents
- Patient’s physician can access pt response, answer questions
- Informed Consent Hotline to answer initial questions
  - CTSI patient research advocate for more detailed queries
- Results to date (>10,000):
  - 86% patients returned signed forms
  - 85% checked “yes” for samples
  - 79% checked “yes” for recontact

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Study Registry and StudyConnect

Study Registry: All (10,200) human subject studies approved by 4 UF IRBs from 2008 to date.

StudyConnect: Web site with 400 active studies for potential research participants to find opportunities.
Implementation Science

• New Program in 2013
• Develop and implement reproducible processes for translating research findings into improvements in health care practice and health
• Examples:
  – Personalized medicine
  – Reduction in readmissions following CHF

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For More Information

• On the web
  – [www.ctsi.ufl.edu](http://www.ctsi.ufl.edu)

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