Helping Researchers Do Research

Introduction to the UF Clinical and Translational Science Institute

Holly Morris, MSN, RN, CCRC, CHRC
Director of CTSI Research Services
Agenda

- NIH CTSA Network
- About the UF CTSI
- CTSI Services and Service Providers
- CTSI Funding support
- CTSI Newsletter
- Q&A
More than 50 medical research institutional “Hubs” across the nation receive CTSA program funding.

These hubs work together to speed the translation of research discovery into improved patient care.
The National Center for Advancing Translational Sciences (NCATS) definition: Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.
About the UF CTSI

- Initial award: 2008
- Third 5-year award from NCATS: July 2019
- Director: Duane A. Mitchell
- Co-Director: Elizabeth Shenkman
- The CTSI was founded to speed the translation of scientific discoveries into improved health by strengthening the university’s ability to conduct clinical and translational research.
About the UF CTSI


- Connect resources, people and ideas

- Expand collaboration and advance translational research across UF’s 16 colleges, the state (including key partnership with FSU), and the national CTSA network.
Navigating the Research Process

- Design a study
- Conduct a study
- Manage data and software
- Use Facilities & Cores
- Recruit participants
- Navigate regulations
- Funding support
No-Cost Consultations

A great way to start

- Project review
- Assistance to identify possible needs
- Discuss all available options
- Connect to service providers and other possible collaborators
- Evaluate available resources
- Make recommendations
- Assist with navigation
- Identify education programs
- Provide letters of support
Services to help you design a study.
Biostatistics, Epidemiology and Research Design (BERD)

Consult, collaborate, educate and promote innovation in tools and methods related to study design and biostatistical issues in CTSI

- Study design – clinical trials, observational studies, cohort, chart review, qualitative, epidemiologic
- Power analysis
- Data analysis
- Data presentation and visualization
- Qualitative research collaborations
- Survey design
- CTSI Design Studio lunch series
- Method development
UF Library Services

The CTSI Library Liaisons serve as a resource for those conducting clinical research at UF.

- LibGuides for clinical research
- Consultations: information needs, literature searches, electronic and print resources, research related tools
- Information-related classes
- Presentations for department meetings and journal clubs
- Collaborate on publications and grants
- Systematic Review service
A partnership between the Health Science Center Libraries and the CTSI

Melissa Rethlefsen, MSLS, AHIP
Associate Dean, George A. Smathers Library
Fackler Director, Health Science Center Libraries

Patti Mc-Call Wright, MA, MLS
Systematic Review Librarian

- Systematic Review: A process of collecting and synthesizing evidence to answer a specific question using a pre-specified protocol
- Standards require librarian/information specialist participation
- Hourly rates are based on faculty librarian salary, associated costs, covidence subscription
- Education: review series, introduction to SR, lectures, presentations, covidence classes
We provide **data** management and **software** assistance.
We help researchers execute discovery, produce scholarly works, manage research activities

**Systems and Operations**
- General IT design and consulting
- Server and database provisioning, support and management
- Application hosting and support
- Informatics platform implementation

**Informatics Services**
- Consulting and design
- Research grant assistance
- Research needs analysis and proposal development
- IDR and other clinical data access
- Software design and development
**REDCap**

A secure, web-based well-developed tool/application that facilitates data capture and management.

- REDCap can support multicenter and/or multiple arm studies.
- You decide who has access to your project and what users can do and see inside your project (‘user rights’).
- A low to no-cost alternative to custom built systems. Two tiered pricing model—you build with some training, or REDCap team builds for you.
- Classes and on-site expert support: CTSI-REDCAP-SUPPORT-L@LISTS.UFL.EDU
**REDCap features**

- Autovalidation of data
- Ability to create calculated fields
- Ability to upload files
- A scheduling module
- The ability to apply branching/skip logic to questions
- Longitudinal data collections, including survey data
- Easily manage a contact list of survey respondents or create a simple survey link for participants
- Ability to develop secure web-based surveys
- Seamless data export to common data analysis packages
- Logging/audit trails
- User rights
- Record locking
- Graphical data view and stats
- Report Builder
- Data quality module
- Training Resources module
Services to help you conduct a study.
Clinical Research Center

**Personnel**
- Experienced research nurses, research coordinators, research assistants, dietician, laboratory support, medical technologist

**Facilities**
- Outpatient facility including 14 exam rooms
- 2 procedure rooms
- Exercise physiology area
- Metabolic kitchen

**More**
- Inpatient research support
- Investigational pharmacy
- Equipment - basal metabolic cart, PFT testing, treadmill, exercise bike, pain testing, ultrasound
Advanced Research Resources

Clinical research project support and services
Available to internal investigators by MOU and Scope of Work

- Partial or Full FTE Personnel
- Clinical Research Nurses
- Research Coordinators
- Research Assistants
- Regulatory support
- Internal Study Monitoring
- Quality Control
Investigational Drug Service (IDS)

Consult with experts on applying human-validated assessment measures of behavioral concomitants of disease or therapeutic interventions.

- Positive pressure US 797 compliant clean room
- Class A1 biological safety cabinet
- Investigational pharmacy
- Protocol consultations
- Receipt, storage and dispensing of investigational product
CTSI Biorepository Services

Institutional Specimen Library
- 47,000* Samples available
- 38,000* COVID-19 related from >1,000 total subjects

*As of September 2020

Clinical Trial Support Services
- Custom kit creation
- Specimen kit distribution, shipping, sample receipt, reconciliation and storage

PI-Initiated Storage Services
- Specimen bank created for the PI or program
- Extensive range of storage options

PI-Directed Studies
- Verify regulatory aspects of the PI research study
- Function as the gatekeeper for IRB/Pathology
Services to help you recruit participants.
Recruitment Center

Assistance to develop your Recruitment Plan

Feasibility, communication strategies, creating recruitment materials and evaluation of recruitment methods.

- Social media recruitment
- HealthStreet
- Integrated Data Repository & Consent2Share
- College of Journalism & Communications
- UF Health Studies listing
- ResearchMatch
- CTSA consortium institutions addressing recruitment challenges.
Integrated Data Repository (IDR)

Access clinical data for cohort identification, recruitment of study population and to answer research questions.

- HIPAA-compliant, IRB-approved “Limited Data Set”
- Cohort Discovery - local, state, national resources
- Find/contact potentially eligible participants
- Identify other collaborators and research sites
- Useful for research and quality and safety initiatives
- Data exploration and analysis
- Planning for grant proposals, clinical trials, protocols
Integrated Data Repository (IDR)

- **i2b2**: a HIPAA-compliant and IRB-approved tool to access information from across the UF Health clinical and research enterprise (e.g. EPIC electronic health records)
- **UF Consent2Share** – patient consent for research contact
Integrated Data Repository (IDR)
Available categories of data from UF Health i2b2

- Patient demographics
- Biorepository specimen availability
- Diagnoses
- Procedures
- Immunizations
- Inpatient and outpatient encounters
- Pain scores

- Patient reported outcomes
- Personalized medicine program data
- Laboratory results
- Medications
- Assessment scores
- Visit locations, visit types
- Other variables
- Consent2Share
OneFlorida Clinical Research Consortium

- Statewide clinical research network and OneFlorida Data Trust database
- Partners include hospitals, clinics, physician practices
- Offers investigators the opportunity to engage in research with ethnically, racially and geographically diverse populations
- Research queries using de-identified patient records within the OneFlorida Data Trust
- Hypothesis generation and study feasibility assessments

Learn more at onefloridaconsortium.org
The ACT Network
Accrual of patients to Clinical Trials

- Developed and powered by the NCATS CTSA Consortium
- Real-time open access platform allowing researchers to explore and validate feasibility for clinical studies.
- Secure, HIPAA-compliant, and IRB-approved
- Available to all researchers at participating sites
- July 2019: 41 sites, 125 million total patients
Cohort Discovery and Feasibility

<table>
<thead>
<tr>
<th>i2b2 instance</th>
<th>Patients</th>
<th>Facts</th>
<th>Geography</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCATS ACT</td>
<td>100M</td>
<td>~50B</td>
<td>National (34 sites)</td>
</tr>
<tr>
<td>OneFlorida</td>
<td>13.2M</td>
<td>14.5B</td>
<td>Florida</td>
</tr>
<tr>
<td>UFHealth - GNV</td>
<td>1.2M</td>
<td>1.1B</td>
<td>Gainesville service area</td>
</tr>
<tr>
<td>UFHealth - JAX</td>
<td>0.7M</td>
<td>0.3B</td>
<td>Jacksonville service area</td>
</tr>
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Community Engagement: HealthStreet

Recruit participants from the community, including underrepresented populations.

HealthStreet aims to:

- Assess medical problems and health concerns from community residents themselves
- Link people, based on their needs and concerns, to medical and social services and opportunities to participate in health research
- Engage in bidirectional, health-promoting communication with and for the community
- Increase the community’s trust in the research enterprise through meaningful collaboration
HealthStreet 4 Pillars

**Assessment**
- Screen for conditions/concerns
- Better health
- Targeted interventions

**Linkage to Care and Research**
- Give referrals
- Navigate to UF research
- Access and parity
- Quality improvement
- Increased relevance and impact of research

**Building Trust**
- Measure research perceptions and trust
- Breaking down walls
- Becoming a community

**Bidirectional Education and Workforce Development**
- Train the next generation
- Provide opportunities for communication within the Learning Health Community
- Building and sustaining the Learning Health Community
Since November 2011

Participants engaged in the community or at HealthStreet
14,471

HealthStreet Consented Members
12,260

- Refused: 2,030
- Ineligible: 181

- Breakoffs: 403

Health Needs Assessments Completed
11,857

- Members Not Linked: 5,618

Members Linked
6,239

- Members Not Navigated: 303

Navigated Members | Navigation Events
5,936 | 12,659

Enrolled Members | Enrollment Events
2,520 | 3,677

- Members Not Enrolled: 3,710
# HealthStreet Diversity

## Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI &gt;30</td>
<td>60%</td>
</tr>
<tr>
<td>High BP</td>
<td>80%</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>56%</td>
</tr>
<tr>
<td>Not Insured</td>
<td>7%</td>
</tr>
<tr>
<td>Not working</td>
<td>65%</td>
</tr>
</tbody>
</table>

The map shows the distribution of these demographics across different counties in Florida.
Services to help you navigate regulations.
Regulatory Knowledge and Support

Aim to help research teams navigate the UF research landscape and the regulatory and compliance environment

- Research process consultations, informed consent consultations, my IRB submissions
- IND, IDE assistance
- ClinicalTrials.gov assistance
- Ethics consults
- Research Subject Advocate
- DSMB assistance by charter
- SOP development
- GLP, GMP, GCP support
Workforce Development programs
Workforce Development

To train and sustain the next generation clinical and translational workforce

- KL2 Multidisciplinary program
- TL1 Predoctoral Training Program
- Clinical Research Professionals training and educational programs
- Mentor Academy
- Masters, Certificate, Concentrations
- Educational Scholarship program
- Bioscience industry workforce
More technologies and services offered by our core facilities.
Biobehavioral Core

Broad expertise in the application of human-validated assessment measures of behavioral concomitants of disease or therapeutic interventions.

Center for Cellular Reprogramming

Services and training for induced Pluripotent Stem Cell (iPSC) derivation and related reprogramming technologies.

Center for Safety, Simulation & Advanced Learning Technologies

Clinician training through simulation in processes, drugs and devices in order to promote patient safety.

Genotyping Core

Consultation and guidance in designing and performing genetics and pharmacogenetics studies, and targeted determination of genotypes on genomic DNA from biological samples.
Human Imaging Core
Infrastructure and support to facilitate research and educational activities using Magnetic Resonance Imaging (MRI) technology, with particular emphasis on translational MRI research in humans.

Southeast Center for Integrated Metabolomics
Metabolomics services for clinical and basic science studies, including mass spectrometry, nuclear magnetic resonance and bioinformatics.

Translational Drug Development Core
Promising compounds need assistance moving from the lab toward clinical trials, which generate the in vivo data needed for continued federal funding and licensing. The TDD core provides services and expertise in bioanalytical drug metabolism and preclinical pharmacokinetics in order to help faculty bridge this gap.
How are CTSI services paid for?

- CTSI Support
  - No-cost consultations
  - Voucher program
  - CTSI Pilot Awards

- Department funds
- Grant budgets
- Contracts line items
CTSI Pilot Programs

Supports the growth of interdisciplinary and investigator-initiated clinical and translational research across UF’s broad range of scientific disciplines.

Types of pilot awards:

- **CTSI Pilot Awards (formerly Traditional, and Patient-Oriented Clinical combined)**
  Focused on translational research

- **Specialized**: Focuses on a specific core or concept (Metabolomics, Translational Communication Research, Pain, Informatics, Precision Health), COVID Rapid Response

- **Translational**: Designed to impact clinical practice – the “Learning Health System”
CTSI Voucher Program

- Covers some CTSI Services
- Funding up to $1,000
- Initial consultations required
- Website request

Voucher Request

Did you know that you can request a no-cost consultation from various CTSI services at any point in your study, even before submitting for IRB approval? CTSI service providers can spend an hour or two advising any researcher at the university. To schedule a consultation with the services listed below, find contact information and further details linked from the Research Services page:

- Biostatistics or Epidemiology
- HealthStreet
- Integrated Data Repository
- Recruitment Center
- REDCap
- Regulatory Support (IND/IDE)
- Regulatory Support (IRB)
- Data Management/Informatics (CTS-IT)
- Other

If you find that you need more assistance after your initial consultation, you may request a voucher by filling out the form linked below.

The CTSI provides vouchers to help support investigators who may have limited resources. Vouchers provide a maximum of $1,000 funding to help cover the cost of services in order to help “unstick” the research process. Complete the below form to apply for a CTSI Service Voucher if you have already consulted with a CTSI service provider (initial consultations are provided to all researchers at no charge), and you require additional service.

VOUCHER REQUEST FORM
Get CTSI news, funding announcements and event updates once a week.
Contact the CTSI

- www.ctsi.ufl.edu
  352.273.8700
- hlmorris@ufl.edu
  352.294.5881
How can we help you?
Questions?