Health Informatics for Clinical and Translational Science: The University of Florida Experience

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The UF CTSI is supported in part by NIH awards UL1 RR029890, KL2 RR029888 and TL1 RR029889
The University of Florida

- 50,116 students
- Gainesville, FL
- 2200 ac campus
- “The Gators,” Gatorade
- 16 colleges
- Land grant, sea grant, space grant, academic health center
- ARWU #68
- $750M in research construction
- 2010 Research funding $678M
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The UF CTSI

• In July of 2009, UF received a $26 million, five year, NIH Clinical and Translational Science Award supporting the UF Clinical and Translational Science Institute (UF CTSI)
  – The UF Office of Research has provided an additional $23 million in support
  – The UF College of Medicine has made $70 million in additional commitments
  – All 16 UF colleges → effort for students, staff, faculty, space, equipment

• The result: an institute designed to transform the university’s ability to conduct clinical and translational science – increasing research capacity, speeding results to application, improving care and human health
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A Catalyst for Collaboration

UF CTSI

CTSA consortium

Corporate Partners

16 UF Colleges

University Partners

Health Care Systems

Community Partners

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Biomedical Informatics

• Overarching Goal
  – Develop and integrate clinical and research data systems to support collaborative CTS and lay groundwork for new academic program in BMI

• Specific Aims
  1. Build/delivery core informatics capabilities – portal, study registry, investigator registry, data registry, sample registry
  2. Build/delivery integrated data repository for research and clinical care
  3. Create academic program

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Michael Conlon, PhD
Informatics Projects

- CTSI Portal – rebuilt. 182 pages, 284 news stories. Daily posts. REDCap, Education and Research Services are top pages
- REDCap infrastructure, service. 467 users. 74 databases. 16,884 forms entered
- Study Registry. All human subject research at UF. 2008-11. 2735 studies coded with a goal of 8234.
- Integrated Data Repository. Comprehensive, enterprise systems and processes for quality reporting and research. I2b2, honest broker
- CTSI Biorepository. OnCore BMS. Integrate automated freezer controls
- Biositemaps. UF #1 in described research resources
- Click Commerce for IRB
- CTSI tracking systems – help desk, vouchers, billing, analytic dashboard
- Budgeting tool for clinical services
- VIVO. International project in research discovery
- CTSA-IP database with U Rochester
- Replace CRC legacy applications
- Health Record Bank for Alachua County
- Portal process map for clinical research
- Health Impacts for Florida – PBRN portal, ShareCenter, REDCap, custom databases
- Consent for Research Contact and Use of Tissue. With UF & Shands, IRB.
- Improving protocol submission process
- Personalized Medicine – genetics repository, IDR, alerts in Epic
Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

About • Research • Education • Community • Contact

News & Events

CTSI Study Registry preview, Dec. 8
The CTSI is hosting a preview of the CTSI Study Registry for interested UF investigators, coordinators, faculty and staff. Members ... Read More

CTSI Seminar, Dec. 7 – Data to Action: UF Family Data Center
The UF CTSI Seminar Series presents: "DATA TO ACTION: UF Family Data Center A Portfolio of Collaboration Opportunities – Data ... Read More

Distinguished Speaker, Nov. 29: William Klein on social psychological approaches to cancer
The Cancer Center Population Science Research Working Group and UF's Southeast Center for Research to Reduce Disparities in Oral Health ... Read More

MORE NEWS

Services for Investigators
Educational Opportunities
CTSI in the Community

Clinical, laboratory, consulting, training and support – the UF CTSI provides over 40 distinct services to investigators involved with clinical and translational science. The CTSI seeks to improve the university’s ability to do science, to make discoveries, to publish results and to translate those results into improved care and improved health. CTSI services include the UF Clinical Research Center,
CTSI Portal

- 4 month project to rebuild an existing portal
- 2 months of information architecture. Collaboration with UF&Shands, campus IT. 8 person team
- 1 month of implementation, editing. WordPress, Shibboleth. 174 pages, 269 news stories, 52 writers and editors. 6 member core group
- One month of testing, finishing.
- Launched January 2011.
- Content maintained by Asst Dir for Communications, CTSI w/ student assistant
- Infrastructure maintained by UF&Shands IT
REDCap

REDCap (Research Electronic Data Capture) is a secure, Web-based application designed to support traditional case report form data capture for your research studies. It is provided at no cost for use with any research project. For those with funding, fee-based configuration services are also available to jump-start a given project.

REDCap was originally developed at Vanderbilt University. The University of Florida and more than 195 other partners now comprise the REDCap Consortium that continues to develop and support the software. Read more about REDCap’s features at the consortium Web site at http://project-redcap.org/.

Using REDCap’s streamlined process for rapidly developing databases, users create a project, define and organize the data they wish to capture, build the related forms and associate them with study events. Other features include automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

REDCap development often takes place before your protocol is reviewed by the IRB, however, an IRB approval letter is required before your REDCap project can be moved into production and begin collecting research data. Copies of subsequent yearly IRB approvals are also required to keep your project active.

Login to or register for REDCap
REDCap Implementation and Support

- REDCap researcher support team – Doug Theriaque (CRC informatics), two assistants
- Shibboleth authentication. UF developed methods provided to the REDCap consortium
- Infrastructure maintained by UF&Shands IT
- Software maintained by REDCap support team
Goal: Create new opportunities for practicing physicians, clinical scientists, students, and the citizens of Florida to collaborate in advancing research and education into the causes, prevention, diagnosis, treatment and cure of human disease.
Welcome

Health IMPACTS for Florida is a unique collaboration between the University of Florida and Florida State University to facilitate community-based clinical research and improve health throughout the state. For its initial research projects, Health IMPACTS for Florida is partnering with primary care practices in the Tallahassee, Jacksonville, Gainesville and Orlando areas.

News & Events

Initial Funding Announcement: UF Press Release
November 15, 2010: UF, FSU receive grant for community-based clinical research

UF CTSI Supplement Award Announcement
June 16, 2011: UF CTSI receives $1.25 million to advance clinical research and personalized medicine

Initial Funding Announcement: FSU Press Release
November 15, 2010: College of Medicine receives grant for community-based clinical research.
Developing Health IMPACTS

• Grant from the State of Florida, CTSA
• Supplement grant from the NIH
• Major development effort to integrate WordPress, REDCap, ShareCenter, custom databases, other software, Sakai.
• iPad, clinic-based data collection
• Infrastructure support by UF&Shands IT under contract from UF CTSI

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Study Registry

• Create a comprehensive database of all human subject research at UF. 2008-current
• Hand collect/classify data from our 4 IRBs
• Develop data maintenance processes for four IRBs to provide data going forward
• Create an on-line participant opportunities site to support enrollment
• 2,246 studies coded
• On-going work to collect additional 6,333 studies
• Review 195 studies with investigators. Launch in December

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# Human Subject Studies at UF

<table>
<thead>
<tr>
<th>IRBs</th>
<th>Health Ctr</th>
<th>Campus</th>
<th>Jacksonville</th>
<th>Western</th>
<th>Total</th>
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<tbody>
<tr>
<td>2011 (est)</td>
<td>695</td>
<td>1217</td>
<td>182</td>
<td>144</td>
<td>2238</td>
</tr>
<tr>
<td>2010</td>
<td>683</td>
<td>1170</td>
<td>171</td>
<td>141</td>
<td>2165</td>
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<tr>
<td>2009</td>
<td>687</td>
<td>1205</td>
<td>161</td>
<td>124</td>
<td>2177</td>
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<tr>
<td>2008</td>
<td>647</td>
<td>1059</td>
<td>153</td>
<td>150</td>
<td>2009</td>
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<tr>
<td>Total</td>
<td>2712</td>
<td>4651</td>
<td>667</td>
<td>559</td>
<td>8589</td>
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</tbody>
</table>

Working with each IRB, the UF CTSI team hand codes each study for 34 attributes including T1-T4 research, keywords, lay description, PI and department information.
VIVO: Enabling National Networking of Scientists

- NIH-funded effort to create an open semantic network of information and tools regarding scientists, their interests, activities and accomplishments
- Seven school development consortium led by UF
- Fifty additional implementations underway. Dozens of partners
- Find people, grants, papers, data, concepts, resources, events, data, studies, projects within and across institutions
- http://vivoweb.org

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VIVO: Enabling National Networking of Scientists

• 3 software releases. Version 1.4 coming in December.
• Adoption by USDA (120,000 + land grants), APA (154,000), 50 US schools, 20 international (8 Australia)
• Six mini-grants – Pitt, Duke, Leicester, Weill, Indiana, Stony Brook
• 14 schools at Implementation Fest, June 23-24. 30 others in various stages of implementation. 50 total.
• Second annual conference, Wash DC, August 24-26. 260 attendees
• 15,000 downloads of software. 1600 members on contact list
• Sustainability – additional grants, 501C3, open source community
• Collaboration with Eagle-I, HSDB, ORCID, SciENCV, Linked Data
• Partnerships with federal agencies, publishers, schools, associations, companies, EU efforts
VIVO Searchlight
A convenient way to find researchers

Searchlight is a small app that automatically shows you VIVO profiles related to the page you're reading.
interleukin-8 secretion, and epithelial cell proliferation. A murine model for ETBF has not been characterized. Specific pathogen-free (SPF) C57BL/6J or germfree 129S6/SvEv mice were orally inoculated with wild-type ETBF (WT-ETBF) strains, a nontoxic strain of B. fragilis (WT-NBF), WT-NBF overexpressing btf (rETBF), or WT-NBF overexpressing a biologically inactive mutated btf (rNTBF). In SPF and germfree mice, ETBF caused colitis but was lethal only in germfree mice. Colonic histopathology demonstrated mucosal thickening with inflammatory cell infiltration, crypt abscesses, and epithelial cell exfoliation, erosion, and ulceration. SPF mice colonized with rETBF mimicked WT-ETBF, whereas rNTBF caused no histopathology. Intestinal epithelial E-cadherin was rapidly cleaved in vivo in WT-ETBF-colonized mice and in vitro in intestinal tissues cultured with purified BFT. ETBF mice colonized for 16 months exhibited persistent colitis. BFT did not directly induce lymphocyte proliferation, dendritic cell stimulation, or Toll-like receptor activation. In conclusion, WT-ETBF induced acute then persistent colitis in SPF mice and rapidly lethal colitis in WT germfree mice. Our data support the hypothesis that chronic colonization with the human commensal ETBF can induce persistent, subclinical colitis in humans.

In 1984, a molecular subgroup of Bacteroides fragilis, enterotoxigenic B. fragilis (ETBF), was identified to cause diarrheal illnesses in livestock (44) and, in 1992, in humans (40). Subsequently, ETBF has been associated with diarrheal disease...
Integrated Data Repository

- Collaborative, large scale effort to construct a comprehensive, secure data warehouse for quality reporting and research. Data from Epic and other clinical systems
- Proof of Concept with Recombinant Data implementing i2b2 completed June 30, 2011. 50 million facts.
- UF CTSI funded two pilot awards in cohort identification for clinical study planning
- Seminars, department presentations
- Participation of UF & Shands IT, IRB, Compliance, Privacy, CTSI, colleges, other centers
- Related projects in consent, biorepository
- Developing roadmap for on-going work
CTSI Funded IDR Pilot Projects

*Database Communication enables Machine Learning Classifiers to predict Perioperative Acute Kidney Injury*
  - Azra Bihorac, MD, Department of Anesthesiology
  - Mark Segal, MD, Division of Nephrology, Hypertension and Transplantation, Department of Medicine

*Comorbidity indices and disability: Targeting recruitment impairment & Identification of iatrogenic mobility impairments*
  - Susan Nayfield, MD, MSc, Institute on Aging
  - Todd Manini, PhD, Institute on Aging
Clinical Translation in Pharmacogenomics

Clopidogrel (Plavix): genetic polymorphism of CYP2C19 leads to reduced ability to activate clopidigrel and increased risk of cardiovascular complication
Personalized Medicine Program
Data Trail – Clopidogrel Pilot

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Informatics for Personalized Medicine

• Project Steering Committee
  – Personalized Medicine Program Manager
    • Informatics Project Manager
      – Bioinformatics Lead
      – Path Lab Lead
      – Integrated Data Repository Lead
      – Clinical Systems Lead

• 24 hour turn around time from sample to alert
• First patients: April 2012
Improving Protocol Submission

- Single research price list
  - Simple confirmation of service
  - Applies to all clinical studies using Shands services
- Click Commerce for IRB
  - On-line protocol submission
  - Simplified process
- Budgeting tool
  - Simplified clinical trial budget creation based on current service rates

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Protocol Development and Approval Time

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<td>Protocol Preparation</td>
<td>45</td>
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<td>Confirmation of Service Pricing</td>
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<td>10</td>
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<tr>
<td>Approval by SAC</td>
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<td>25</td>
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<td>Approval by RAC</td>
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<td>10</td>
<td>7</td>
<td>5</td>
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<tr>
<td>Approval by IRB</td>
<td>28</td>
<td>28</td>
<td>28</td>
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BMI Academic Program

• Lecture Series
  – Third academic year for full series mixing invited speakers with UF faculty. Organized two seminars on IDR.

• Faculty meetings
  – Monthly series. Fourteen faculty from across UF departments and colleges. Build community of informaticians. Identify opportunities of interest

• Academic Program Planning with Dean’s Office
BMIP Year 4

- BMI Academic Program. Faculty affiliations, hires. Training program.
- Comprehensive enterprise architecture for research informatics
- Personalized Medicine. Sample collection, bioinformatics, IDR, EHR
- VIVO. Open source community. i2b2. Continue growth
- Health IMPACTS. iPad/REDCap data collection. Network portal
- Research Participant Registry. In IDR
- Genetic Data repository. In IDR
- Data registry. In IDR
- Specimen registry from biorepository. In IDR
- Consent data. In IDR
- Conversion of legacy applications – eDSMB, eAERS, CRC scheduling
- CTSI Service Delivery systems – ticketing, vouchers, billing, reporting
Clinical and Translational Research Building

• CTSI headquarters
• Ambulatory Clinical Research Center and targeted research programs
• Biostatistics, BMI, Epidemiology, and Health Policy
• Training Programs (pre and post doctoral)
• 80,000 ft² dedicated space
• Incorporated with Institute of Aging (NIH funded; 40,000 ft²)
• February 2013
For More Information

• On the web
  – www.ctsi.ufl.edu

• Call
  – 352-273-8700

• Email
  – info@ctsi.ufl.edu