

**University of Miami Clinical and Translational Science Institute (Miami CTSI)
Highlights, Milestones, and Challenges**

A. Programs, Cores, Clinical Research Units

1. **Overview: Administrative Core**
2. **Biomedical Informatics**
 - EPIC Electronic Health Record
3. **Research Ethics**
 - Bioethics Program and the W.H.O. Collaborating Center in Ethics and Global Health Policy
 - Collaborative Institutional Training Initiative (CITI)
4. **Novel Clinical & Translational Methods, Technologies & Resources**
 - Center for Advanced Microscopy (Gables Campus Core)
 - Ophthalmology Mass Spectrometry Core
 - Electron Microscopy Core
 - Miami Project to Cure Paralysis High Content Screening Core
5. **BioResource**
6. **Pilot and Collaborative Clinical & Translational Studies**
7. **Study Design & Biostatistics**
 - Biostatistics Consulting and Collaboration Core
8. **Regulatory Knowledge & Support**
 - Office of Regulatory Support and Quality Assurance
9. **¡Alianza! Miami Clinical Research Participants & Partnerships**
 - Behavioral Medicine Research Center
 - Center for AIDS Research
 - Clinical Pharmacology Research Unit
 - Clinical Research Center
 - El Centro – Culturally-Tailored Hispanic Research Center
 - Florida Node Alliance of the Drug Abuse Clinical Trials Network
 - Pediatric Clinical Research Center
 - Sylvester Comprehensive Cancer Center Clinical Research Services
10. **Research Education, Training, & Career Development**
 - Master of Science in Clinical and Translational Investigation
 - Mentored Translational Research Scholars Program (K12)
 - Scientists and Engineers Expanding Diversity and Success (SEEDS)
 - Networking Program
 - Mentoring Program
 - Professional Development Programs
 - Translational Science Boot Camp
11. **Community Engagement & Cultural Diversity Component**
 - Sylvester Comprehensive Cancer Center Disparities & Community Outreach Core
12. **Evaluation and Tracking**

B. Committees/Programs Meetings

1. **CTSI Leadership Team** – Meets weekly, usually more often to address issues, problem solve, manage operations, advance work on Component-specific and overall CTSI strategic goals
2. **CTSI Administrative Core Team** – Meets weekly
3. **Executive Committee** – Meets monthly
4. **External Advisory** – Meets twice a year, once in person and once via conference call
5. **Internal Advisory** – Meets quarterly
6. **Scientific Advisory** – Meets quarterly
7. **Office of Research and Innovative Medicine-CTSI Alignment** – Meets monthly
8. **Provost Meetings** – Initially, met monthly. Decreased as CTSI start-up stabilized
9. **Institutional Research Resource Council** – Met monthly in conjunction with Scientific Advisory Committee. It quickly proved of value to the University, and was thus incorporated into the School of Medicine's Research Cabinet.

10. **CTSI Community Advisory** – Meets twice a year
11. **Operational Leadership** (all Component Directors) – Meets monthly
12. **Component-Specific Working Groups** – Meets twice-weekly, or more as needed to accomplish tasks.
13. **CTSI-CFAR Integration** – Meets every two months. Strong synergies exist, as several component co-directors also have leadership roles in the CFAR (G. Scott, N. Schneiderman, M. Fischl). Additionally, one of the CTSI pilots funded in Y1 was in collaboration with the CFAR.
14. **CTSI-NeuroNext Integration** – Meets every two months

C. Highlights

1. **One Florida – Collaboration with the University of Florida CTSI** – we have developed a collaborative agreement with the UF CTSI in regards to research, research cores, and work to garner funding from the State of Florida for One Florida activities. A formal partnership is being developed to expedite future collaborations. To date, representatives from the Miami CTSI participated in the UF CTSI Research Day and vice versa. The UF CTSI PI and our CTSI's Senior Advisor, Dr. Richard Bookman, presented the One Florida concept at our CaneSearch Research Day. A UF-UM joint seed grant application will be funded by the Miami CTSI, and synergistic UM-UF efforts in Metabolomics, Microbiome and Bionanotech are being explored.
2. **Alignment with UM School of Medicine** – The Chief Strategy Officer for the medical enterprise, Dr. Elaine Van der Put, took on the role of Chief of Strategic Operations for the CTSI in order to guarantee the full alignment of the CTSI with the direction of the entire medical enterprise, and vice versa.
3. **Alignment with Research Office** – We are committed to fully align CTSI activities with the Office of Research and Innovative Medicine. To that end, we meet monthly with the Interim Executive Dean for Research and weekly in the Research Cabinet. The CTSI leads efforts to advance system-wide harmonization and process improvements in such areas as research cores, clinical research facilities, regulatory knowledge and support consultation, workforce development starting with clinical research coordinators' training and career ladders, standardizing job descriptions, and exploring the potential for streamlining clinical research with our community partner, Jackson Memorial Hospital.
4. **IRB Electronic Workflow, Information Processing, and IT System Improvements** – We are in the final stages of revamping the current inefficient system by funding an upgrade to eProst 7. The new system will:
 - Automate IRB submissions through all phases of a research study: initial submission, modifications, reportable new information, and continuing reviews.
 - Use intuitive screens and workflows to help research personnel remain compliant with applicable regulations.
 - Reduce administrative burden. The software supports individual and committee review processes, maintains compliance correspondence and organizes information for tracking and audits.
5. **CaneSearch** – The Community Advisory Board has identified Obesity as a major health concern for the diverse South Florida community, and the theme was adopted as the focus of the inaugural research day, "CaneSearch." Keynote speakers included Dr. John Ruffin, Director of the National Center on Minority Health and Health Disparities, and Dr. David Nelson, Director of the UF CTSI. The daylong event, attended by more than 500 people, was comprised of a poster session that featured 70 scientific posters on obesity-related topics, 40 core and central resource posters, and 10 community partner posters. The event also featured a Collaborative Research Exchange Forum, at which speakers gave presentations on topics ranging from obesity science to interventions. The panel discussions brought together experts from various disciplines, including medicine, architecture, Miami-Dade County Parks and Open Spaces, psychiatry, engineering, pediatrics, surgery, and genetics.
6. **Hack-a-thon** – Concurrent to CaneSearch and in conjunction with Lift 1428, a Miami-based innovation, design, & strategy firm, the Miami CTSI hosted *Impact Obesity*, a unique hack-a-thon event that sought to inspire innovative business ideas that incorporate technology to manage and reduce obesity in minority communities. Over 2 days, 5 teams that included web developers, programmers, graphic artists, medical and Ph.D. students collaborated on solutions to fight obesity. Teams had access to UM researchers and healthcare experts and development support from Rokk3r Labs, an entrepreneurial start-up company. Winners were awarded CoWork Space at the Miami Innovation Center and an invitation to submit for further funding from the Miami CTSI. The first place winner was a project called "No Obese City," a multilingual portal to engage parents and children to live a healthy lifestyle. Parents with children in school lunch programs would be able to track their child's nutritional intake and daily physical activity.

D. CTSA Consortium Activities

- **Trusted Broker Systems** – The Miami CTSI organized and sponsored a 2-day “Biobank Trusted Broker Governance” Workshop that involved seven CTSI Institutions: Vanderbilt, U Florida, South Carolina Translational Research Institute; U Michigan Institute for Clinical & Health Research; Johns Hopkins Berman Institute of Bioethics; Duke Translational Medicine Institute, and the Miami CTSI. The team will work on several initiatives going forward to obtain consensus of Biobank Trusted Broker Governance best practices, and, importantly engage their respective CTSA and the CTSA Consortium KFCs in the effort.
- **Work Force Development** – The Miami CTSI developed a new clinical research coordinator career ladder and job description framework that will be closely aligned with a new training curriculum currently being worked on. Our work closely followed what was developed and presented at the 2010 NIH Conference on Clinical Research Nursing that focused on various roles involved. Building on our work, we organized and sponsored a day-long retreat of representatives from the Harvard, Cincinnati, USC, Michigan, and Miami CTSA to plan to develop a curriculum for training clinical research coordinators that could be offered across the CTSA Consortium. The CTSA Clinical Research Management Subcommittee has subsequently expressed interest in supporting the effort.
- **Voting Membership in CTSA committees:**
 - Tracie Miller, ¡Alianza! Component, Child Health Oversight Committee
 - Shari Messinger, Study Design Component, BERD
 - Ken Goodman, Research Ethics Component, Clinical Research Ethics Committee
 - Jonelle Wright, CTSI Associate Director, Clinical Research Management Committee
 - JoNell Potter, ¡Alianza! Component, Clinical Services Core Committee
 - Raquel Perez, Communications Director, Communications Committee
 - Olveen Carrasquillo, Community Component, Community Engagement Committee
 - Hendricks Brown, Study Design Component, Comparative Effectiveness Research Committee
 - Neil Schneiderman, Research Education Component, Education and Career Development Committee
 - Sara Czaja, Evaluation Component, Evaluation Committee
 - Nick Tsinoremas, Biomedical Informatics Component, Informatics Committee
 - Norma Kenyon, Novel and Translation Methods Component, Public-Private Partnership Committee
 - Jonelle Wright, Regulatory Knowledge Component, Regulatory Knowledge Committee

E. Milestones

1. Personnel

- Year 1 CTSI personnel hires include the following:
 - Elaine Van der Put, PhD, MSPH, Chief of Strategic Operations (Administrative Core)
 - Sheela Dominguez, CRA, Director of Strategic Operations (Administrative Core)
 - Stellamarina Covelli, Fiscal Manager (Administrative Core)
 - Raquel Perez, Communications Manager/Web Content Editor (Administrative Core)
 - Yvonne Mejias, Fiscal Assistant (Administrative Core)
 - Lynn Suarezapecheche, MBA, Executive Assistant (Administrative Core)
 - Patricia Avissar, MS, Research Navigator (Administrative Core)
 - Joann Krasnoff, PhD, Senior Manager of Research Support (¡Alianza!)
 - Zeporia Kettles, Senior Administrative Assistant (¡Alianza!)
 - Carlos Sandoval, Program Coordinator (Research Education & Training)
- Next hires/personnel additions will include:
 - Research Navigator
 - Research Subject Advocate (RSA), Associate RSA, and RSA Coordinator/QI Specialist
 - Regulatory Quality Improvement Specialists (2)
 - Database Programmer/Developer for the Data Environment
 - Web Applications Developer for building the Virtual Research Commons
 - Chief Academic Technology Officer (to be appointed 10% from existing UM)
 - CITI Specialist
 - Clinical Research Center Nurse Manager
 - Executive Coordinator and Community Research Associate for Community
 - Evaluation Data Engineer

2. CTSI Virtual Commons

- In the process of expanding current Web Environment to accommodate Virtual Research Commons
- In the process of designing the SharePoint foundation that will aggregate multiple knowledge/information/resource repositories across the University

3. Community Engagement & Cultural Diversity

- Developed health disparities and CBPR training programs and curriculum

4. Research Ethics

- Convened CTSI Consortium Trusted Broker Governance Expert Workshop in Miami
- In conjunction with BioResource, Biomedical Informatics, and Regulatory Components, started developing structures, policies, and rules for University CTSI Trusted Broker Governance
- Launched required Research Ethics course in “Master of Science in Clinical Translational Investigation” program
- Developed CITI-based training module in cultural diversity, in process of developing training modules for clinical research coordinators and compliance topics

5. Novel Clinical & Translational Methods, Technologies & Resources

- Created University policy on core & shared resources, including access for external users
- Completely reorganized University innovation team, technology advancement infrastructure, and procedures for IP assessment
- Successfully implemented CaneSearch Research Day and Hackathon
- Awarded 2 Novel Methods Development projects and 4 Coulter Innovation projects
- Formed Drug Discovery group that meets regularly
- Hired Senior Fellow from “big pharma” to jumpstart network and provide commercial perspective
- Extensive interactions with Life Science Technology Park to identify potential corporate partners

6. Biomedical Informatics

- Developed first version of IT data environment for exploration of de-identified EPIC EHR data for feasibility and retrospective studies Implementation and roll-out of REDCap Enterprise Research Database Tool

7. BioResource

- Initiated Users Advisory Group and Biospecimen Adjudication Committee
- Established a Cost Recovery Center (e.g., NIH Cancer Genome Atlas)
- RTS DNA storage robot system is fully operational
- In collaboration with Research Ethics, Regulatory, and Biomedical Informatics Components, we are developing the interface between EPIC EHR and clinical laboratory and pathology information systems

8. Pilot and Collaborative Clinical & Translational Studies

- Implemented multi-layered review process for pilot studies, including Biostatistics and Ethics reviews, an NIH Study Section-type review panel, and a post-meeting program review in Grant Y1 funding of four Pilot projects and two Supplemental CTSI Service Credits awards

9. Study Design & Biostatistics

- Offered consulting services; implemented Biostatistics clinics and roundtables
- Funded three methods development pilot projects
- Integrated NIH Center for Prevention Implementation Methodology and NIH-funded P30 Center on Implementation Science Methodology into Component activities
- Launched M.S. and Ph.D. in Biostatistics, the latter with 7 students already
- Used Biostatistics Consulting and Collaborative Core to train Biostatistics PhD students
- Increased NIH and NSF funded grants in methodology at the University
- Established Multi-University Collaboration networks

10. Regulatory Knowledge & Support

- Developed DSMP and research participant advocacy framework
- Successfully established Consult service
- IRB Share is up and running
- In collaboration with institutional Office of Regulatory Support and Quality Assurance, and ¡Alianza!, Regulatory, Research Ethics, and Research Training Components, initiated Work Force Development project detailed above. This has been identified as a high priority by University and School of Medicine leadership.

11. ¡Alianza! Miami Clinical Research Participants & Partnerships

- See above Work Force Development project
- Developing certification process for clinical research professionals

12. Research Education, Training, & Career Development

- Research Boot Camp and Master's in Clinical and Translational Investigation are operational
- Awarded two K12s and initiated University-wide mentoring program

F. Challenges

1. Institutional Transformation

- The goal of transforming UM's research enterprise in regard to research governance, process infrastructure (policies, procedures), research practice standards, resource utilization, data use, bi-directional relationship between investigators and community and interdisciplinarity/team science requires a significant change in organizational culture, decision making, communication strategies, institutional reward mechanisms, and individual mindsets.
- Harmonizing SOPs, personnel policies, and administrative forms/procedures and building consistent business plans for adoption across the various clinical research facilities, pilot award mechanisms, and research resource cores currently functioning as standalone entities that currently function disparately.

2. Communication

- Effective communication has been identified as an Institutional hurdle that will be carefully addressed in Y2 of the CTSI. The CTSI will explore improvements in communication strategies, not only for its own mission and services, but also to inform and guide the University research community at large.

3. Operational Logistics

- The considerable lag time experienced in our grant being awarded requires extra effort and further organizational assessment to confirm applicability of what was proposed in our 2010 CTSA grant application for today's institutional context.
- Extended time and energy required to hire appropriate individuals into new positions and manage the operational and interpersonal "settling in" process.
- Identifying, organizing, and synchronizing appropriate frameworks, Component and overall CTSI metrics, and data collection and analysis procedures to produce CTSI evaluations that a) deliver what we committed to in our grant application, b) make available data/information required in the APR, and c) meet CTSA Consortium expectations/demands.
- Managing meetings – getting the right balance in frequency and required participants to get things done, communicate effectively, and move the work along, but not cause meeting fatigue or stifle integration and synergy.

G. Program Integration and Innovation – As described in Section D. Milestones.

H. Future Directions – Please refer to Component narratives. Highlights include:

- Consolidate under One Florida in collaboration with University of Florida CTSI
- As identified by CTSI Component Leadership, communications and CTSI awareness (both internally and in the community) will be key strategic priorities moving forward
- Continue to expand and integrate throughout the University of Miami research enterprise our theme of culturalized health sciences, as well as through the CTSA National Consortium
- Establish BioResource Governance
- Transform University investigator culture toward bi-directionality in community-engaged research, and improve on bi-directional research relationship with our community partners
- Establish University-wide Center on Statistical Sciences
- Establish federation of University pilot initiatives
- Attain reduced time to IRB approval via implementation of eProst 7
- Establish a Data Environment that can capitalize on diverse sources of human data
- Improve clinical research quality through: mentoring of clinical investigators, establishing a new career ladder and corresponding training program for clinical research professionals, and establishing minimum certification standards for clinical research facilities
- Attain better acceptance in Promotions & Tenure for team scientists
- Stimulate innovation and translation into clinical practice and community health