

Miami CTSI Year 2 Highlights, Milestones, and Challenges

A. Integration of Programs, Cores, Clinical Research Units

The following programs, cores, clinical research units, and University leadership appointments strengthen strategic institutional integration of CTSI initiatives/activities and build system-wide synergies:

1. Community Engagement & Cultural Diversity Program

- Director, Dr. Kobetz, was recently appointed Sylvester Cancer Center's Associate Director for Disparities & Community Outreach

2. Research Ethics

- Director, Dr. Goodman, heads the UM Bioethics Program and the W.H.O. Collaborating Center in Ethics and Global Health Policy
- Director, Dr. Braunschweiger is Founder CEO of Collaborative Institutional Training Initiative (CITI)

3. Novel Clinical & Translational Methods, Technologies & Resources

- Strengthening ability to support and leverage, bi-directionally, scientific initiatives leading to commercialization, Program Director, Dr. Kenyon, is UM Vice Provost for Innovation and Director of the Wallace H. Coulter Center for Translational Research.
- Director, Dr. Vance, is Human Genomics Institute's Genomic Education & Outreach Center Director
- Director, Dr. Cheung, is VA Senior Career Research Scientist

4. Biomedical Informatics

- Director, Dr. Tsinoremas, is founding Director of the Center for Computational Science
- Director, Dr. Seo, is UM Chief Research Information Officer and medical school Chief Medical Informatics Officer

5. BioResource

- Director, Dr. Cote, is UM's newly formed Biomedical Nanotechnology Institute's Director
- Co-Director, Dr. McCauley, Institute for Human Genomics' Biorepository Core Associate Director

6. Pilot and Collaborative Clinical & Translational Studies

Leaders of the following have established a federation of pilot and collaborative clinical and translational research funding mechanisms.

- Center for Psycho-Oncology Research
- Behavioral Medicine Research Center
- Sylvester Cancer Center
- Glaser Foundation Research Awards
- Biomedical Nanotechnology Institute
- Miami Center for AIDS Research
- UM Scientific Awards Committee
- Miami Project to Cure Paralysis
- Urology Research
- Medical School Office of Research

7. Study Design & Biostatistics

- Program Co-Director, Dr. Messinger, Biostatistics Consulting and Collaboration Core Director
- Program Co-Director, Dr. Rao, is establishing a University-wide Center for Statistical Sciences

8. Regulatory Knowledge & Support

- Advisory Panelist, Dr. Jayaweera, Associate Vice Provost for Human Subject Research
- Advisory Panelist, Ms. Coltes, Director for Regulatory Affairs and Educational Initiatives in the Human Subjects Research Office
- Advisory Panelist, Ms. Stamates, Director of Regulatory Support and Quality Assurance
- Advisory Panelist, Ms. Ann Glasse, Clinical Research Operations & Regulatory Support Director

9. ¡Alianza! Miami Clinical Research Participants & Partnerships

- Director, Dr. Potter, is an IRB Vice Chair
- Director, Dr. Salathe, is Clinical Research Center Director

10. Research Education, Training, & Career Development

- Director, Dr. Schneiderman, is Behavioral Medicine Research Center Director, directs two NIH T32s and is site PI of the NHLBI longitudinal multi-center Hispanic Community Health Study.

B. Committees/Programs Meetings – Please refer to Administrative Narrative

C. Highlights

1. **Miami CTSI** – Formally established the University-wide Miami Clinical & Translational Science Institute

- Permanent space renovated and CTSI Research Commons opened, serving as CTSI home office and collaborative space for University-wide clinical and translational activities.
 - Legislation #2012-40(B) passed by the Faculty Senate and formally approved by President Shalala.
 - Because of our unique leadership structure in which the medical school's Chief Strategy Officer serves as CTSI Chief of Strategic Operations, the CTSI enjoys a prominent role in the Institution's 2014 Strategic Plan: leading efforts to streamline institutional research processes/ overcoming barriers (e.g. IRB 7, UResearch, Clinical Research Professionals network, training, & career ladders; clinical research policy and procedure templates; UF-UM reciprocal DSMB arrangement); advancing institutional research processes/investigator-focused services/expertise in culturalized health sciences and culturally sensitive research that focuses on health disparities; better capturing race/ethnicity data in clinical admission process to increase capacity for health disparity research in diverse populations attending UM clinical settings; strategically promoting and leveraging team science/research collaboration, especially in top-funded areas; Research Commons to encourage research networking; and extensive CTSI research education and mentorship programs.
 - Recognized by EAC as having made "remarkable" strides, in just 18 months, in engaging the University community and serving as a catalyst for clinical and translational research with broad engagement of senior institutional leadership in the CTSI.
2. **URIDE (University Research Integrated Data Environment)** – Developed and implemented data connectivity from EPIC Electronic Medical Record.
 3. **One Florida – Collaboration with the University of Florida CTSI** – Developed an agreement with the UF CTSI to collaborate in research and in garnering funding from the State of Florida for One Florida. Year 2 activities: 1) began developing a reciprocal DSMB agreement between the two institutions for instances when local experts are precluded from serving on DSMBs because of COI issues, 2) the two CTSI ethics programs worked on appropriate consent for research-related secondary clinical data use, 3) expanded the UF Southeast Center for Integrated Metabolomics (SECIM) 2014 RFA for Pilot & Feasibility Project Awards to include UM, 4) brought UM and UF researchers together to build a translational research collaboration in muscular dystrophy with an emphasis on minority recruitment.
 4. **CTSI-RIM/Institutional Alignment** – CTSI activities are now fully aligned with those of the medical school Office of Research. This is facilitated by meeting monthly with the Acting Senior Executive Dean for Research and weekly in the medical school's Research Cabinet, the latter to introduce new CTSI initiatives, identify areas needing process improvements that the CTSI can orchestrate, build research collaborations, and orchestrate operations. Each month, the Research Cabinet dedicates a meeting solely to reviewing, brainstorming, and soliciting feedback/input on CTSI initiatives/activities/services. The CTSI is taking the lead or helping in several CTSI collaborative initiatives to advance system-wide harmonization or process improvements in such areas as clinical research facilities, URIDE, IT management of core laboratories, individualized regulatory knowledge and support consultation, IRB infrastructure, research subject advocacy, AAHRPP accreditation, workforce development starting with standardizing clinical research professionals' job descriptions and career development career ladders, and developing programs for clinical research professionals' networking and training.
 5. **IRB Electronic Workflow, Information Processing, and IT System Improvements** – The CTSI Biomedical Informatics Program completely revamped the IRB's outdated system with IRB 7 to:
 - Automate initial submissions, modifications, reportable new information, and continuing reviews.
 - Use intuitive screens/workflows to help research personnel remain compliant with regulations.
 - Reduce administrative burden: the software supports individual and committee review processes, maintains compliance correspondence and organizes information for tracking and audits.
 6. **New IDC distribution guidelines to advance Team Science** – Instituted new guidelines for multi-unit grants to operationalize the guiding principle that IDC/F&A: a) follows direct costs, b) is divided among the units that support faculty and the units that support space in research awards.
 7. **Novel Clinical & Translational Methods, Technologies & Resources**
 - Instituted an innovative new role, the Entrepreneur in Residence (EIR). This person (Bob Williamson, from New World Angels, a group of private investors that provides equity capital to early-stage entrepreneurial companies in Florida) paired specific technologies (i.e. a novel anti-inflammatory agent, a novel anesthetic, a paradigm-shifting technology for cancer research/drug

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discovery/therapy, a mobile healthcare app, and others), with successful business people (who, in turn, become voluntary EIRs) who help develop business plans and serve as start-up CEOs.

- From last year's CANESEARCh, formed a scientific collaboration to test a novel nanotechnology platform to deliver HIV therapeutic agents across blood brain barrier in a nonhuman primate model.

8. Work Force Development – To standardize role definition, pay and benefits, and requisite expertise, work experience, and skills of clinical research professionals, with HR collaboration and institutional approval, constructed a new clinical research coordinator career ladder with accompanying job descriptions that will be aligned with a mandatory training curriculum that is currently being developed.

9. Pilot and Collaborative Clinical & Translational Studies – Implemented a system-wide Federation Umbrella for University Pilot Research Programs.

10. CTSA Consortium Activities

- **CTSI Steering Committee presentation on Lessons Learned in Advancing Innovation in Education and Training** – “Clinical Research Professionals Workforce Development”, presentation by Szapocznik and Wright.
- **2014 CTSA GCP Certification Subcommittee** – Drs. Braunschweiger and Wright continue actively in this subcommittee led by CTSA Steering Committee member, Dr. Barohn.

D. Milestones/Timelines (including proposed changes)

1. Personnel

- Please see Appendix #1 for Year 2 hires

2. Community Engagement & Cultural Diversity

- Extensively adapted race/ethnic designations for clinical patients to more accurately depict race and ethnicity composition in EMR.
- Compiled directory (name, contact information, educational background, content area of interest, countries and types of communities) of 188 UM faculty conducting community-engaged research.

3. Research Ethics

- Conducted research ethics analysis, identified elements to be addressed in URIDE implementation.
- In conjunction with BioResource, Biomedical Informatics, and Regulatory Programs, developed structures, policies, and rules for University CTSI Trusted Governance.
- Submitted to Institutional senior leadership formal analysis of current clinical consent for research and recommendations on feasibility and risk of alternate models and governance approaches.

4. Novel Clinical & Translational Methods, Technologies & Resources

- Established permanent offices of Chief Innovation Officer in Life Science Technology Park.
- Completely reorganized University innovation team, technology advancement infrastructure, and procedures for IP assessment; hired new Tech Transfer Director and Entrepreneur in Residence.
- Successfully implemented second annual CaneSearch Day.
- In a new Coulter Center collaboration, partnered to award 6 Novel Methods Development projects that span cancer, schizophrenia and glaucoma. This unique program awards funds *and* matches awardees to a team that engages them in the “Coulter Process”: a) delineating the “killer” experiment that will convince potential business partners that a technology has merit, and b) pairing researchers with clinicians, business people, and tech transfer liaison.
- Director Cheung mentored Juan Ruiz first UM student to receive "Rhodes" Fellowship of Science.

5. Biomedical Informatics

- Subject recruitment and data capture via REDCap and Velos (Appendix #2 reports utilization data).
- Development and deployment of University-wide research website (URResearch) in collaboration with Vice Provost for Research. Website launch to be accomplished by May 31, 2014.

6. BioResource

- In collaboration with Research Ethics, Regulatory, and Biomedical Informatics Programs, developed interface between EPIC EHR and clinical laboratory and pathology information systems.
- SOPs implemented at Cancer Center Tissue Bank to serve as standard for BioResource Program: participant consent, IRB and privacy protocols, sample procurement, data storage and transfer.
- Initial integration of BioResource data systems into URIDE using pilot database (caTissue) to allow users to query de-identified longitudinal clinical and sample data.

7. Pilot and Collaborative Clinical & Translational Studies

- Implemented system-wide Federation Umbrella for Pilot Research Programs.
- Federation Pilot Program Leaders consensus to engage Department Chairs in identifying and recruiting qualified reviewers for pilot applications (Appendix #5).

8. Study Design & Biostatistics

- University-wide Consultation Core at full capacity. Biostatistics clinics and roundtables continue.
- Funded three statistical methods development pilot projects.

9. Regulatory Knowledge & Support

- Developed DSMP and research participant advocacy framework.
- Initiated consult service.
- Approval for UM-UF Reciprocal DSMB arrangement obtained from UF Research VP, UM Research Vice Provost, Executive Research Dean, and HSRO Associate Vice Provost.
- Institutional approval obtained for new job description structure and format for all medical school research personnel. In Stage 1, University HR formally adopted, for the very first time, explicit elements of regulatory compliance and human subjects' protections and training mandates for responsible conduct of research in all research job descriptions.
- Initiated first ever IRB Grand Rounds.
- Approval obtained from Institutional leadership for IRBShare, contract signed and operational.

10. ¡Alianza! Miami Clinical Research Participants & Partnerships

- Developed "Universal" operating procedures for use across ¡Alianza! sites.
- Active and engaged Network for Clinical Research Professionals (NCRP) established and ongoing.
- Piloted two day-long U-Way Workshops; 100% evaluated workshop positively.

11. Research Education, Training, & Career Development

- Research Boot Camp and Master's in Clinical and Translational Investigation filled to capacity.
- Initiated University-wide mentoring program and awarded two K12s.
- Scientists and Engineers Expanding Diversity and Success (SEEDS): University-wide program that offers networking, mentoring, professional development, and a Translational Science Boot Camp.

12. Tracking and Evaluation

- Outcome and process metrics for overall CTSI and each Program developed.

E. Challenges

1. Institutional Transformation

- Transforming research process infrastructure (policies, procedures, resources, standards) and support for team science requires significant change in organizational culture, decision making, communication strategies, and institutional reward mechanisms.
- Identifying high level vision-focused objectives and impact metrics (added value of CTSI to Institution) achievable during the life of the grant and being able to collect and analyze data appropriate to defined metrics.
- Strong relationships between CTSI and clinical enterprise other nationally recognized research programs, and centers of research excellence need developing to leverage scientific opportunity and achievements, expand CTSI's presence in areas important to research translation to clinical application, and build capacity for culturalized health sciences across the University.
- Concomitantly, we need a more robust focus on technology transfer to fully leverage and support extensive UInnovation achievements to advance "translation" of discovery with an impact on health.

2. Operational Logistics

- Managing meetings – getting right balance in frequency and attendees to maintain communication, get things done, move impactful work along, and strengthen synergies, all without meeting fatigue.
- Some of our exceptional leaders initially recruited to serve as Program Directors have been promoted and/or their research programs have flourished, so much so that they no longer have bandwidth to meet CTSI responsibilities. Yet, they want to keep their CTSI roles and there may be reasons to do so. Though challenging, we are now trying to reconfigure CTSI management to better leverage institutional leaders' role in CTSI while increasing operational efficiency.

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- Establishing baseline database for key foci, vision-focused objectives matched to Program-specific as well as overall CTSI impact measures, and data collection and analysis procedures to: a) meet APR tracking requirements, b) guide key management decisions, and c) support quantitative/qualitative evaluations to demonstrate impact and prepare for future grant renewal.
- Need to reconfigure CTSI pilot mechanism to effectively leverage \$3M in awards by Federation constituents and better incentivize CTSI strategic aims and promote interdisciplinarity and team science. This next year, we will reduce award size to allow more targeted awards, offer CTSI service credits to Federation awards, take part in Research Cabinet studio sessions (focused research development meetings); expand the Federation; and leverage and support successful institutional funding mechanisms with exceptional return on investment.
- Huge array of process and outcomes metrics initially developed across CTSI Programs provides useful framework for establishing priorities for tracking and evaluation, but inadequate to gauge impact. We are now cutting back while developing vision-focused objectives and impact metrics.

F. Program Integration and Innovation – As described in Section A. Programs, Cores, Clinical Research Units, and Section D. Milestones.

G. Institutional Support and Commitment –

The Institution is in line with providing the committed 5 year Institutional Matching funds to the CTSI.

H. Facilitating Multisite Research and CTSI Impact Within Partner Institutions

1. **Grant-supported CTSI-Jackson Health System Clinician-Researcher** –
2. **Race/ethnicity of Clinical Admissions** – Critical to our region, CTSI and JHS teamed to extensively adapt designations to more accurately depict race/ethnicity composition for minority-engaged research.
3. **JHS Research Director, Dr. Heros**, builds research bridges between JHS and UM. He has agreed to serve as JHS representative to CTSI, organizing activities to elevate JHS as equal partner in scientific development and build and sustain strong research teams across the two institutions. In Grant Yr. 3, the CTSI will support 75% FTE of an expert research liaison/facilitator to assist Dr. Heros in the day-to-day JHS management of UM-generated grant proposals, study protocols, and implementation plans to ensure successful integration and sustained research collaboration between JHS and the University.
4. **VA Geriatrics, Research, Education and Clinical Center Deputy Director, Dr. Flores** – serves as CTSI-VA liaison for research collaborations.
5. **VA Senior Career Research Scientist, Dr. Cheung** – serves as Novel Methods, Technologies, & Resources Program Director, bridging the CTSI with the VAMC as well as the School of Engineering.
6. **Center for Computational Sciences Director of Engagement, Dr. Khuri** – an expert in team science, is charged with building CTSI team science initiatives across UM campuses: medical center (housing UM, JHS, & VA), Gables, and Marine Science.
7. **Assistant Provost for Research, Dr. McCafferty** – In Grant Yr. 3, we will leverage her expertise, resources, and Institutional leadership (oversees cores and team science for the University), through her new role as CTSI Novel Methods, Technologies, & Resources Program Co-Director.

I. Future Directions – Please refer to Program narratives.