

Miami CTSI Self Evaluation Report

a. Evaluation Framework and Plan

The Miami Clinical & Translational Science Institute (CTSI) is the University of Miami's (UM) home for interdisciplinary clinical and translational (C/T) research and training. Its institutional partners are Jackson Memorial Hospital and the Miami VA Healthcare System. Our self-evaluation goals are to 1) Monitor progress of the Miami CTSI and its programs against plan; 2) Use feedback from tracking and evaluation activities to make course corrections, where necessary; 3) Monitor longitudinal impact of the CTSI on clinical and translational research activities at the University; and 4) Document transformation.

The programs and initiatives of the Miami CTSI are built around its five main aims. Programs developed plans that summarize the specific aims, timelines, objectives and process measures. Progress against plan is monitored by the evaluation team, in collaboration with each program. Additionally, each program presents a monthly update on progress and initiatives, inviting input from the CTSI leadership. The sections below present each of the five aims of Miami CTSI and highlight Year 2 progress towards each goal. The detailed program narratives and appendices, found elsewhere in this document, report metrics and progress against plan in detail for each CTSI Program.

a.1. CTSI AIM 1: Establish the Foundation and provide the leadership for the CTSI governance as the ongoing impetus for culturalized health science.

The vision of this aim is to transform UM's fragmented infrastructure into an integrated research process infrastructure under a new participatory governance to promote C/T research, interdisciplinary collaboration, and the efficient use and sharing of resources. Impact will be assessed by evaluating the effectiveness of the governance structure in streamlining the interaction and integration among the CTSI Programs, using evaluation feedback to chart course corrections where necessary and incorporating the feedback of the CTSI Executive Committee and External Advisory Committee (EAC). The first annual EAC meeting of the Miami CTSI was held on January 23, 2014. Most of their recommendation will be implemented in Year 3 and can be found in the EAC report section.

The CTSI Executive Committee (details in the administrative narrative) is a multi-disciplinary group composed of the top research leadership at the University, including the Vice-Provost for Research and the Executive Dean for Research at the Miller School of Medicine.

Among several other actions taken by the CTSI governance to advance clinical and translational research were:

1. Collaborated with the Vice Provost for Research Office to deploy a university wide website UResearch by May 31, 2014;
2. Initiated workflow analysis to identify barriers and opportunities for expediting C/T research and obtain baseline metrics for research processes; and
3. Actively promoted CTSI participation in university Research Cabinet monthly sessions.

a.2. CTSI AIM 2: Provide a secure, HIPAA and regulatory-compliant virtual research environment that builds *interoperability* and offers maximum *interconnectivity* among faculty, partners, and community-based operations.

The long-term goal is to facilitate communications among the CTSI, partner institutions and the national CTSA consortium. Evaluation will be performed by tracking successful development of resources, expertise, and training in data management, capture, integration, analysis, and data sharing.

URIDE Intersection Project: In Year 2, the CTSI Biomedical Informatics team led the successful development of the University Research Informatics Data Environment (URIDE) in collaboration with the BioResource and Research Ethics Programs. URIDE is a large scale data services atmosphere where de-identified data from multiple clinical and basic sciences systems can be explored in preparation for research, prospective and retrospective analysis. Year 2 progress includes implementation of data connectivity from Epic EMR to URIDE and incorporation of the BioResource data systems into the URIDE Phase 1 project, as well as increased functionality and interactivity of the data environment.

CITI Platform: A module on “Cultural Competence in Research Training” was added to the CITI platform as part of the broader CITI training initiative for Clinical Research Coordinators and Administrators. In addition, eight new modules/courses were developed in Year 2, details of which are available in the Program narrative.

a.3. CTSI AIM 3: Transform research processes and clinical research capabilities to support teams of multidisciplinary C/T scientists and clinicians on successful research initiatives; Serve as academic home for C/T research.

The longitudinal impact of this aim will be to create and *sustain* an academic home for C/T research. This will be accomplished through activities focused on service excellence and processes to accelerate C/T scientific discoveries

Research Commons: The establishment of the Research Commons, adjacent to CTSI’s administrative offices, was a major milestone in the establishment of a home for C/T Research at the University of Miami. The infrastructure is composed of meeting spaces, administrative support, interactive technology, etc. Instructional and collaborative sessions are already being regularly held.

The Research Commons is the central hub for all C/T activities, serviced by the CTSI “home” team. The open collaborative space became functional in December 2013. Table 1 illustrates the range of requests or activities processed by CTSI personnel in Year 2. The first annual CTSI Awareness Survey will be deployed on April 1, 2014 to gauge university-wide awareness of CTSI resources and services and improve communication of CTSI services where needed.

Table 1. Research Commons Year 2 Activities/Service Requests

Service Categories	TOTAL
Biostatistics Core and Consultation	291
Community Consultation	184
Education/Training	128
Funding opportunities	86
Seminars/Workshops/Symposiums	26
Ethics Consultation	20

CTSI Website: The CTSI website offers investigators an electronic resource that showcases availability and exchange of CTSI resources, expertise, technologies, and training programs across specialties. Traffic flow is monitored using Google Analytics and tracks which features are being utilized and what areas may require improvement (see Appendix #1 for website traffic). A common form system to direct and track all service

requests is currently being designed by the Biomedical Informatics team and will be fully deployed in Year 3. The specific automated form for pilot awards application and tracking is already fully functional.

URResearch: A university-wide research website is being developed in collaboration with the Office of the Vice Provost for Research. The infrastructure has been developed by the CTSI, and the website is pending content migration/development at the University level. The website is expected to be launched by May 31, 2014.

Research Process Infrastructure: A major system upgrade to IRB 7 was successfully finalized in December 2013. The system was integrated with REDCap and Velos for subject recruitment and data capture (see Appendix #2 for REDCap and Velos utilization data). Longitudinal impact in clinical research processes will be monitored by tracking three national CTSA common metrics (IRB submission to approval, studies meeting accrual goals, time from notice of grant award to study opening) and compared to baseline data to gauge improvement.

a.4. CTSI AIM 4: Promulgate the discipline of C/T research in academic roles and build the professional and technical workforce needed to sustain successful interdisciplinary research teams.

Accomplishment of this aim will be evaluated by the quality, efficiency and effectiveness of research education, training initiatives, and career development programs.

Research Education, Training, and Career Development Program is responsible for providing an institutional umbrella for educational resources, coursework, mentoring and degree opportunities that focus on translational science for individuals and the community; and mentored programs to early career investigators, students and professionals in C/T science. The program narrative and activities are located elsewhere in this report. Evaluation is conducted using a set of quantitative and qualitative metrics including satisfaction surveys and longitudinal tracking of the trainees' scientific productivity (see Appendix #9 and #10).

In Year 2, the program conducted two six-week grant writing workshops in an effort to target investigators submitting K and R type grants. The first workshop was conducted in June-July 2013 and the second workshop was conducted in January-February 2014, with 1:1 interaction and feedback on participants' grants. Over 28 faculty across the university participated in these workshops and received feedback on their grants, many of which were subsequently submitted to various agencies. Evaluations from the participants indicated that the teaching and learning methods promoted understanding of key concepts and the knowledge and skills developed through the workshop would be relevant in the future as well. Feedback from the participants will also be used to customize and improve future workshops. Additionally, the Program conducted a 40-hour Foundations of Translational Sciences Bootcamp that provided an introduction and foundation for translational research to graduate students, medical students, postdoctoral fellows, junior faculty and early career researchers. The Bootcamp had over 108 participants. Evaluation from the participants indicated increased interest towards and improved understanding of C/T research.

Collaborative efforts between CTSI Programs such as ¡Alianza!, Regulatory Knowledge and Support, and Research Education have geared towards the education and training of clinical research professionals. One such initiative is the Network for Clinical Research Professionals (NCRP), which in Year 2 offered six seminars with over 540 attendees in total from UM and invited community partner institutions. Additionally, two pilot workshops (UWay) were organized to educate research support staff on standardized UM research processes (see Appendix #8 for details). In Year 3, these workshops will be rolled out across the broader UM research community via a combination of online and video resources, as well as in-person sessions.

a.5. CTSI AIM 5: Institutionalize the knowledge of culturally-competent and community-engaged research.

The long-term vision of the Miami CTSI is to affect a shift among investigators from thinking of the community as a means (e.g., recruitment) to an end (e.g., a study with community participants), to an understanding of improving our community's health as the true end goal. The longitudinal impact will be evaluated by tracking participatory academic-community research collaboration, and overcoming real/perceived barriers to community research.

Establishing practice-based bi-directional relationships between the community and academia is still in the developmental phase. In Year 2, there was an active emphasis on including cultural content in CTSI activities via CaneSearch themes, Pilot Program focus, Study Design & Biostatistics, Regulatory, Biomedical Informatics, Research Education, and BioResource Programs. Activities of each Program are described in their corresponding narratives and appendices elsewhere in this document. The overarching theme of the second annual research symposium CaneSearch held on February 20, 2014 was neuroscience, with a focus on HIV and drug abuse – two significant health issues prevalent in the South Florida community and identified as being of the utmost importance by our Community Advisory Board at their meeting in April 2013. A new collaboration as a direct result from this event is being established to test a novel nanotechnology platform for delivery of HIV therapeutic agents across the blood brain barrier in a nonhuman primate model.

Additionally, during Year 2, the Community Engagement and Cultural Diversity Program faculty and staff had 107 discrete events involving interactions and/or the provision of support services to UM faculty (proposal development and writing, methodology and data consultations, data collection instrument development, obtaining letters of support, lectures, recruitment strategies, engagement of community partners) as well as had 77 discrete events involving interactions and/or provision of support services to outside organizations (local, state, and national). These activities included assisting with proposals, assisting with outreach activities, funding, reviewing applications, editing translations, and developing curriculum content.

b. Future Timelines

Evaluation of the Miami CTSI will be transitioning in Year 3 to have a greater overall focus on *impact*, with less emphasis placed on process and activity measures as these mechanisms mature.

AIM 1: CTSI governance. In Year 3, evaluation will be focused on measuring the effectiveness of reconfiguring the CTSI structure/process to better leverage institutional leadership's role in CTSI while increasing efficiency in operations, based on EAC feedback.

AIM 2: Virtual Research Environment. CTSI will engage a committee of medical doctors advising further development of the URIDE platform and define/address steps needed to expand URIDE to include data from health system partners. Future research initiatives with implications for evaluation include exploring CTSI-VA-EMR IT research applications.

AIM 3: Academic home for C/T research. Feedback from the awareness and CTSI user satisfaction surveys will be used to conduct improvement planning with the Programs to improve the academic home. Activities to increase collaboration are being planned for Year 3 in the Research Commons space, and the impact of these activities on the incidence of collaborations and new projects will also be measured.

AIM 4: Education of Professional and Technical Workforce. Evaluation in Year 3 will be conducted by tracking activities outlined in the Education Program narrative. Additionally, we will analyze the results of the grant writing workshop, bootcamp, and mentor-mentee surveys and monitor the development, implementation and improvement in these programs based on the survey feedback.

AIM 5: Culturally competent and community engaged research. The Evaluation Program will track and evaluate the consultative services and support provided to the university faculty and community partners. A new initiative based on EAC feedback with implication for evaluation is leveraging MD/MPH students for moving evidenced-based practices into the community (i.e. public health strategies targeting cancer and CVD).

Miami CTSI Program Narratives

Administrative Core

Biomedical Informatics

Research Ethics

Novel Clinical & Translational Methods, Technologies & Resources

BioResource

Pilot & Collaborative Translational & Clinical Studies

Study Design and Biostatistics

Regulatory Knowledge and Support

¡Alianza! The Miami Center for Research Participation and Partnership

Research Education, Training, and Career Development

Community Engagement and Cultural Diversity

Tracking and Evaluation

Miami CTSI Administrative Core (“Home Team”)

A. PERSONNEL

Leadership

José Szapocznik, Ph.D., PI and Director, Miami CTSI, Chair, Department of Public Health Sciences, University of Miami Miller School of Medicine
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Jonelle Wright, Ph.D., Co-Investigator and Associate Director, Miami CTSI

Elaine Van der Put, Ph.D., M.S.P.H., Chief of Strategic Operations, Miami CTSI Chief Strategy Officer, University of Miami Miller School of Medicine

Executive Committee

John Bixby, Ph.D., Vice Provost for Research
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Omaida Velazquez, M.D., Ph.D., Miller School of Medicine Executive Dean for Research, Research Education & Innovative Medicine

Stephen Nimer, M.D., Director, Sylvester Comprehensive Cancer Center
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Ralph Sacco, M.D., MS, Chair, Department of Neurology

Neil Schneiderman, Ph.D., Professor, Department of Psychology

Other Personnel

Richard Bookman, Ph.D., Senior Advisor, Director of “Intersection Project”
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Sheela Dominguez, M.B.A., CRA, Director of Strategic Operations

Daru Ransford, Sr. Manager, Business Operations

Stellamarina Covelli, Fiscal Manager

Patricia Avissar, M.S., Research Navigator
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Raquel Perez, Communications Manager/Website Content Editor

Shavon Jefferson, Fiscal Analyst

Lynn Suarezapecheche, MBA, Executive Assistant
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B. GOAL

Provide administrative, fiscal and programmatic support to all CTSI programs. Coordinate inter-program activities and align programs with CTSI’s overall mission. This group is responsible for Governance, Planning, Organizational Development, Events, and Communications of the CTSI. In addition, infrastructure, administrative, organization, and logistical support is provided to the Programs in order for them to achieve their major milestones.

C. CHARACTERISTICS

1. Overview of Functions:

- a. Governance: The Chief Strategy Officer for the Medical School is a member of the CTSI leadership team. This helps align University, Medical School and CTSI strategic goals. The CTSI leadership group participates in the weekly Research Cabinet, held by the medical school Office of Research.
- b. Research Navigation: Support for all Institutional researchers in regards to existence and access to core facilities, funding opportunities, research services, etc.
- c. Project management of major program and inter-program initiatives, such as Pilot Projects and Mentored Career Awards coordination and support.
- d. Dr. Richard Bookman is responsible for the coordination of the four programs (Biomedical Informatics, BioResource, Ethics, and Regulatory) involved in our most complex project (URIDE), the development of an integrated data system where EMR, bio samples, laboratory and other clinical and research data are organized around a master patient index, protected by a trusted governance system.
- e. Fiscal: budget management and reporting, purchasing, expenditures approval and control, capital asset management.
- f. Communications and Marketing: Internal (University of Miami) and External (Consortium, community) communications include press releases, requests for applications for funding opportunities, announcement and marketing of services provided by the CTSI.
- g. CTSI website design, content development, and management.
- h. Event Management: Organization of all major events, including External Advisory Committee, NIH Program Officer visit, CaneSearch (annual research symposium), Community Advisory Board meeting, major seminars and forums, etc.
- i. Coordination of internal and external reporting, including Progress reports.
- j. Human Resources: organizational chart, position description, recruiting, onboarding, training, evaluation, payroll, vacation tracking, and effort reporting.
- k. Facilities: space management, telephones, furniture; purchase and allocation of computers, equipment and supplies for all CTSI programs.

- l. Customer relations: Documentation and dissemination of information regarding CTSI programs, services, cores and personnel.
- m. Administrative Support to all programs: scheduling, travel, reporting, agendas, presentations.
- 2. Progress:
 - a. Personnel: recruitment of 21 new personnel (Appendix #1), posting, selection, hiring, onboarding.
 - b. CTSI Headquarters: the Miami CTSI now has a physical Research Commons space, comprised of 2,400 contiguous square feet in the Clinical Research Building at the Medical Campus, a home to our clinical and translational research community. The Research Commons has been transformative for convening staff and functions in one area, available to provide consultations and answer questions. It now houses a staff of twelve which include: Research Navigator, Associate Research Subject Advocate, Communications/Fiscal/Operations management and staff as well as some program managers. In addition to modular work stations and offices, there is a conference room equipped with teleconferencing equipment and two collaborative areas for investigators to seek consultations, hold collaborative sessions, program meetings, etc.
 - c. Committee/Program Meetings:

CTSI Leadership Team	Meets weekly to address issues, manage operations, advance work on strategic goals.
CTSI Administrative Team	Composed of the staff listed in Section A plus 7 staff members assigned to programs. Led by the Chief of Strategic Operations, meets weekly to enhance communications, harmonize information between programs and look for synergies between CTSI initiatives.
Executive Committee	Meets monthly.
External Advisory Committee	Meets twice a year, once in person and once via conference call.
Office of Research, Research Training, and Innovative Medicine-CTSI Alignment	Meets monthly.
Provost Meetings	Bi-annual updates.
CTSI Community Advisory Board	Meets annually.
Operational Leadership (all Program Directors)	Meets monthly.
Program-Specific Working Groups	Meet monthly or more, as needed.
CTSI-CFAR Integration	Meets every two months.
CTSI-NeuroNext Integration	Meets every two months.

- d. Operational Support
 - Support for Pilot and Collaborative Projects: Support in creation and communication of RFA for annual pilot program as well as development of automated online application forms. Compilation of application, selection of reviewers, review process, coordination of material for review committee, feedback to awardees and applicants.
 - Support for Research Education program: Developing, reviewing, and awarding Mentored Career Development Awards (KL2). Compilation of applications, selection of reviewers, review process, coordination of material for review committee, feedback to awardees and applicants.
 - Support for Novel Methods component with overall coordination of CaneSearch, University-wide Research Symposium held February 20, 2014. This year's event focused on neuroscience research, including translational approach to HIV/AIDS, drug abuse, addiction, and obesity- areas identified by our community advisors as critical community health issues. Attended by several hundred people, the day was comprised of a morning panel discussion on a bedside-to-bench approach to translational medicine and the role of industry-academic collaboration, a poster session featuring 60 scientific posters and 40 core facility and central resource posters, and a Collaborative Research Exchange Forum, where speakers gave focused talks on the theme. Keynote speakers included Dr. Nora Volkow, Director of the National Institute on Drug Abuse, Dr. Habibeh Koshbouei, associate professor of neuroscience and psychiatry at the University of Florida, Dr. Madhavan Nair, professor and founding chair of the Department of Immunology at Florida International University, and the CTSI's PI, Dr. José Szapocznik, professor and chair of the Department of Public Health Sciences. The scientific poster with the most merit was awarded with vouchers usable for services in UM's core facilities. (see Appendix #4 for more details about CaneSearch)
- e. Coordinated the first Community Advisory Board meeting held on April 29, 2013.
- f. Coordinated the first External Advisory Committee meeting on January 23, 2014.
- g. Presentations: A total of 17 presentations were delivered at departmental faculty meetings to promote CTSI services and funding opportunities. Nine other presentations were delivered to additional audiences gather input on improving UM's research infrastructure. Some highlights were:

- Dr. Elaine Van der Put, Miami CTSI's Chief of Strategic Operations, presented regular updates on the CTSI's progress to the Core Executive Leadership Group of the Miller School of Medicine. This group is comprised of the Dean of the Miller School of Medicine, the Chief Operations Officer of the Health System, the Executive Deans for Research, Clinical and Education, the CFO, and the Chiefs of Human Resources and Information Technology.
 - Bimonthly updates of CTSI progress and activities to the Medical School Research Cabinet
- h. Coordination and Logistical support for two grant writing workshops.
 - i. Software Carpentry Boot camp held on Jan. 27-28, 2014 held for graduate students and postdocs focusing on the fundamentals of writing scripts and software to analyze data, with focus on R and Python programming languages, to improve informatics sophistication within the research community. This boot camp integrated Biomedical Informatics, Education, Biostatistics and Ethics.
 - j. Developed Miami CTSI's second Annual Progress Report.
 - k. CTSI/CFAR alignment and collaborations: Active onboarding and training of Melanie Weiss, senior administrator for the CFAR: Administrative tools, SOPS, guidelines, best practices and processes developed since the implementation of the CTSI were shared. The CTSI process and automated forms for pilot applications was already adopted and is being utilized for their current pilot awards.
 - l. Implemented first customer satisfaction survey for CTSI services. Survey results showed overwhelming satisfaction with services being provided. Satisfaction ratings (1= very dissatisfied to 5= very satisfied)

Core/Service	Please rate your overall satisfaction with the service you received.	Was the turnaround time satisfactory?	Were all your questions answered/addressed satisfactorily?
Combined Average Rating	4.2	4.3	4.1
Biostatistics Collaboration and Consulting Core	3.5	3.9	3.4
Clinical Research Center (CRC)	4.5	4.6	4.5
Community Engagement Consultation	4.3	4.3	4.3
Research Navigator	5	5	5
Pilot applications	4.5	4.3	4.2
K12 applications	4.5	4.5	4.4

3. Marketing & Communication Activities

- CTSI Website Update: Content development has continued, including an expanded navigation and automated mailing list signup. Monthly traffic to the site averages 3,264 page views and is growing. In addition, CTSI social media accounts were launched for Twitter and LinkedIn. (see Appendix #1)
- Developed a strategic communications plan outlining goals, resources, tactics and challenges
- Collaborated with UHealth Marketing team to craft and launch CTSI “visual identity”, which serves as our official brand and improves visibility and understanding of the CTSI with our stakeholders.
- Cultivated a mailing list that has grown to more than 800 subscribers.
- Wrote and published nine full length articles and three press releases on CTSI events and activities

4. Major accomplishments and impact

- A new Strategic Plan was developed for the Medical School. Since the Medical School's Chief Strategy Officer is part of the CTSI leadership, there is total alignment between the CTSI mission and the new strategic plan. (see Appendix #12 for strategic plan with areas of synergy highlighted)
- Development and deployment of the university-wide research website (URsearch) in collaboration with the Office of the Vice Provost for Research. This initiative has been of utmost important for the research community for several years. The infrastructure was developed, and the website is pending content migration/development at the University level. The website will be launched by May 31, 2014.
- Positive outcome of customer satisfaction survey.
- CTSI-CFAR Integration – Meets every two months to build collaboration among the two centers.
- Through our Community Engagement and Cultural Diversity Program Director, we have successfully developed a partnership and collaboration with the Sylvester Comprehensive Cancer Center and the Jay Weiss Center for Social Medicine and Health Equity

D. PLANS FOR COMING YEAR

1. Planning and execution of first Miami CTSI Strategic Planning full-day retreat.
2. Planning, marketing and logistical support for key events, such as CaneSearch.
3. Jackson Health System (JHS) Research Director, Dr. Roberto 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. The CTSI will support 0.75 FTE of an expert research liaison/facilitator to assist Dr. Heros in the daily 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.

Miami CTSI Biomedical Informatics Program

Data and metrics for this program can be found in Appendix #2

A. PERSONNEL **Leadership:** David Seo, MD, Director; Nick Tsinoremas, PhD, Director
Other Personnel: Leah Bamford, Clinical Applications and Data Warehouse Project Manager; Luz Maristany, Biomedical Research Informatics Program Manager

B. GOALS

The goal of this program is to provide the communication foundation for the Miami CTSI, build interconnectivity and interoperability among Miami CTSI programs, develop an integrated data environment that facilitates data sharing across the continuum of clinical and translational research, and educate and train current and future researchers in approaches and techniques in biomedical informatics.

C. PROGRESS AND PLANS

AIM 1: Catalyze communications among the CTSI and its partners.

1. Year 2 Plan

- a. Expansion of the UM CTSI website with the framework to support the Virtual Research Commons
 - i. Designing the SharePoint foundation that will facilitate the aggregation of various knowledge repositories around the University
 - ii. Work with Communications Manager to develop and populate CTSI Website with content.
- b. Develop a phased project plan for the implementation of the CTSI website and initiate Phase I, a repository for SOP's and other documentation, while moving towards Virtual Research Commons platform.

Year 2 Changes

Priority shifted from Virtual Research Commons to development and deployment of university-wide research website (URResearch) in collaboration with the Vice Provost for Research.

2. Year 2 Progress

- a. Developed Virtual Research Commons and collaborative research tools.
 - i. In the planning stage for a knowledge management tool, with framework and infrastructure completed to house internal intranet.
 - ii. Expanding the Research Collaboration Networking Platform.
 - iii. Research study search engine optimization.
- b. Initial implementation of the UM CTSI public facing website (see Appendix #2 for website traffic).
- c. Development of public website for all research at the University of Miami, based on feedback from the research community and leadership that deemed this the highest priority. The infrastructure has been developed, completion of project is pending content migration/development at the University level. The website will be launched by May 31, 2014.

3. Year 3 Plans

- a. Continue development of Virtual Research Commons and collaborative research tools.
- b. Provide training and promote investigator usage of SciVal,
- c. Develop online automated tools for request and tracking of CTSI services

AIM 2: Expand and develop resources, expertise and tools for data capture, management, integration, analysis and data sharing.

1. Year 2 Plan

- a. Continue implementation of the Clinical Data Environment. Continue rollout of the Business Objects Business Intelligence tools to facilitate access to clinical information by the research community. Continue development of information pipeline for clinical data repository to URIDE

- b. Engage in extensive discussion with the Ethics component, IRB and other University authorities regarding the Trusted Broker organization to define the policies and operational procedures for PHI data access and sharing for research
- c. Develop the first version of “Concepto”, the URIDE concept query tool.
- d. Interview additional investigators to gather feedback of the “Concepto” query tool; refine initial use cases with additional features. Continue the engagement with the Bioresource program and develop a searchable tool for all participating biorepositories
- e. Complete major upgrade of the Epic EMR which brings with it a dedicated interface to connect with research systems, as well as a new research billing scheduling system.

Year 2 Changes

Support the implementation of IRB-7 and InfoED update from version 12 to 13. These software platforms were purchased with CTSI support at the end of Year 1.

2. Year 2 Progress

- a. New tools and integrative services developed.
 - i. Implemented IRB 7, with subject recruitment and data capture via REDCap and Velos (see Appendix #2 for REDCap and Velos utilization data).
 - ii. Upgraded infoED from version 12 to 13.
 - iii. Extensive analysis of WebCAMP for tracking purposes.
 - iv. Implemented data connectivity from Epic EMR to the University Research Data Environment (URIDE).
 - v. Pilot project for iPad-based data capture by patients.
- b. Expanded and contributed to the overall security plan around clinical data.
 - i. Establishment of data connectivity from Epic EMR to URIDE.
- c. Provided support and consultation in bioinformatics and data mining. (Appendix #2)
 - i. Developed metrics for the capture of research projects/studies and eProst.
 - ii. Captured customer satisfaction with information services and consultations (Appendix #2).

3. Year 3 Plans

- a. Develop new tools and integrative services.
 - i. Refine IRB 7 process and contribute to curriculum for IRB, Velos, and Compliance training.
 - ii. Continued infrastructure support of three WebCAMP modules in collaboration with the CTSI Administrative group, deployment of additional modules.
 - iii. Continue to recruit collaborators from the UM clinical research community, in collaboration with the Office of Research, to provide feedback on URIDE features.
 - iv. Further design and develop URIDE search tool to automatically update queries and statistics from EMR and BioResource databases.
- b. Expand and contribute to the overall security plan around clinical data.
 - i. Collaborate with IT security on the development of seminars on secure data platforms.
 - ii. Development and implementation of URIDE data de-identification schema.
- c. Provide support and consultation in bioinformatics and data mining.
 - i. Improve support and usage of InfoED and eProst based on feedback from services provided.

AIM 3: Expand and develop education, training and mentorship in Biomedical Informatics to advance clinical/translational science.

1. Year 2 Plan

- a. Expand access to New Tools and Training. Meet regularly with the previously identify user group to further refine and introduce new features to the URIDE search tool.
- b. Collaborate with Research Education program to further explore the options on Masters of Science in Clinical and Translational Investigation Development. By the end of this year we expect to have completed the feasibility analysis and articulate a course of action

2. Year 2 Progress

- a. Ongoing training in bioinformatics provided. (Appendix #2)
 - i. Conceptualized development of educational presentations for: disease ontologies, data mining, and controlled vocabularies.
 - ii. Participated in CTSI/Center for Computational Sciences Boot Camp for young researchers.
- b. Development of online educational modules in bioinformatics.
 - i. Developed a computer-based training module regarding how to access the EMR system for research purposes.

3. Year 3 Plans

- a. Explore new opportunities for and continue providing training in bioinformatics.
- b. Development of online educational modules in bioinformatics.
 - i. Collaborate with Research Education Program to provide input for online learning modules for URIDE.

A. MAJOR ACCOMPLISHMENTS

- Development and deployment of university-wide research website (URresearch) in collaboration with the Vice Provost for Research. This initiative has been of utmost important for the research community for several years. The infrastructure has been developed, and the website is pending content migration/development at the University level. The website will be launched by May 31, 2014
- Implemented IRB 7, with subject recruitment and data capture via REDCap and Velos (see Appendix #2 for REDCap and Velos utilization data).
- Implemented data connectivity from Epic EMR to the University Research Data Environment (URIDE).

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, we participated in consortium activities and meetings, as well as working with partner CTSA institutions.

Miami CTSI Research Ethics Program

Data and metrics for this program can be found in Appendix #3

A. PERSONNEL

Leadership: Kenneth W. Goodman, PhD, Director; Paul Braunschweiger, PhD, Director

Other Personnel: Robin N. Fiore, PhD, Trusted Governance Official; Reid Cushman, PhD, Trusted Governance Official

B. GOALS

The goal of the Research Ethics program is to integrate programs and expertise related to clinical and translational research ethics at UM, provide expertise in educational, community, clinical and “culturalized” research ethics for all CTSI activities and promote integration and training in the responsible conduct of research (RCR) across the enterprise. The Research Ethics program will also promote and engage in research ethics research.

C. PROGRESS AND PLANS

AIM 1: Develop and integrate ethics services, activities, and processes into all levels of clinical and translational research via: research ethics consultation and research ethics education.

1. Year 2 Plan

- a. Implement new CITI Program course for Clinical Research Coordinators and Administrators (CRC/CRA) (in conjunction with Harvard CTSI and USC CTSI) and our CTSI programs, Alianza!, Education and Regulatory.
- b. Continue Research Ethics Consultation Service RECS support across the institution
 - i. Develop and roll out a short training experience
 - ii. Address integration issues in support of transformative goals.
- c. Continue CTSI/UM Ethics Program Seminar series to provide programming and education including *Dialogues in Research Ethics* and existing Grand Rounds series.
- d. Develop joint ethics projects with the University of Florida CTSI on research ethics issues, initiatives and projects.

2. Year 2 Progress

- a. Ethics considerations in CTSI-initiated programs and deliverables systematically reviewed and incorporated through Research Ethics Consultation Service (RECS) activities.
 - i. Implemented new RECS systems, including SOP documentation, new online request procedure, and new consult response format.
 - ii. Updated RECS website content.
 - iii. RECS activities (consults and review of systems):
 - Research Ethics Consult review of all Miami CTSI pilot awards (6) and K12 proposals (13); individual investigator-initiated reviews (4) (Appendix #3)
 - URIDE review
 - Department of Radiation Oncology Databank protocols (HSRO request)
 - EVENTBRITE review (RECS initiated)
- b. Increased participation of C/T researchers/service providers in Research Ethics Education activities by offering new types of activities and leveraging existing educational offerings:
 - i. Three sessions of *Dialogues in Research Ethics* (DRE) currently available online
 - ii. Satisfaction instrument deployed for DRE
 - iii. Ethics faculty participation in collaborative UM C/T education efforts, including IRB Grand Rounds (2), CTSI seminars (2), Dept. of Medicine Grand Rounds (1), Radiation Oncology Grand Rounds (1)
 - iv. FDA Clinical Trial Seminar – Ethics faculty participated in session on consent
 - v. Software Carpentry Bootcamp – research ethics elements integrated into workshop
- c. CITI Program
 - i. Added queries (under protocols) regarding racial, ethnic, and gender diversity

ii. Eight new modules and courses developed in 2013-14:

Humanitarian Use Devices (HUD)	Responsible Conduct of Research Refresher Course
Working with Zebra Fish in a Research Setting Course	Dual Use Research
Wildlife Research Course	Research Ethics in Society
Post Approval Monitoring Course	Cultural Competence in Research

iii. Published CITI *Good Clinical Practice Guide* to accompany online GCP course completed by more than 40,000 learners globally and more than 250 learners at UM

3. Year 3 Plans

- a. Systematically review and incorporate Ethics considerations in CTSI-initiated programs and deliverables through Research Ethics Consultation Service (RECS) activities
 - i. Develop/deploy new satisfaction instrument following RECS consults; analyze results
 - ii. Increase visibility and utility of RECS throughout UM
 - iii. Conduct RECS activities – consults and review of systems
 - iv. Develop RECS Systems Review tools, set of questions, considerations for analysis
- b. Increase participation of C/T researchers/service providers in Research Ethics Education activities by offering new types of activities and leveraging existing educational offerings:
 - i. Incorporate and publish sessions on translational and culturalized medicine topics in DRE colloquia
 - ii. Participate in collaborative C/T educational efforts
 - iii. Analyt results of satisfaction instrument
- c. CITI Program
 - i. Access data on racial, ethnic, and gender diversity of CITI learners
 - ii. New CITI modules, courses, and materials under development:

Vulnerable Subjects	Responsible Conduct of Research
IRB Administration Course	Community Based Research
Institutional Official – Human Subjects Research Course	Clinical Research Coordinator Guidebook (CITI Program Version)
Institutional Official – Animal Care and Use Course	Social and Behavioral Research Guide
Disaster Planning for the Research Enterprise	Conflicts of Interest Guide
Working with Independent IRBs	

AIM 2: Incorporate ethics analysis into the development of new research administrative services, new research tools, and new data environments throughout the Miami CTSI.

1. Year 2 Plan

- a. Continue working with the BioResources, Biomedical Informatics, and Regulatory programs to complete the design of all elements of the Biodata Trustee System (BTS) including structure, design, rules, policies and procedures.
- b. Complete a manuscript based on the February 2013 Biodata Trustee System (BTS) governance Workshop.
- c. Present on Biodata Trustee Systems at the American Society for Bioethics and Humanities 2013 annual meeting in conjunction with other CTSA institutions.

2. Year 2 Progress

- a. Development of institutional initiative to implement “broad” consent for research use of clinical information and samples.
 - i. Research and preparation for January 2014 Trusted Governance workshop
 - ii. Prepared briefing on changes necessary to facilitate ethically grounded collection/utilization of EMR and biospecimens at UHealth hospitals
- b. Ethics review of Biomedical Informatics and BioResource projects, products and procedures developed and implemented in collaboration with these and Regulatory Program
 - i. Completed/continuing consults and reviews for: URIDE, Radiation Oncology Databank Consent

3. Year 3 Plans

- a. Development of institutional initiative to implement “broad” consent for research use of clinical information and samples.

- i. Develop timeline, decision tree, to move from current to proposed regime
- ii. Draft templates for consent forms; Draft policies for trusted governance systems
- iii. Consult regarding training for new consent and governance (ongoing through Year 4)
- b. Provide Ethics review of Biomedical Informatics and BioResource projects, products and procedures developed and implemented in collaboration with these and Regulatory Program
 - i. Consult regarding continuing development of URIDE at Jackson Health System, Veterans Affairs Medical Center, and integration of Health Choice Network

AIM 3: Conduct research on research ethics, including topics such as diversity, culture and other ethics C/T topics and promote findings within and beyond the Miami CTSI.

1. Year 2 Plan

- a. Evaluate existing Collaborative Institutional Training Initiative (CITI) survey instruments and delivery systems, retrieve and analyze data from existing surveys to improve systems.
- b. Update research protocols and begin deploying new surveys on focused research ethics topics relating to diversity and related Miami CTSI topics.

2. Year 2 Progress

- a. Development of research on research ethics:
 - i. Hired CITI Program Research Analyst to initiate research projects
 - ii. Received HSRO approval for research on research ethics protocols.
- b. Apply research findings on research ethics to improve C/T research:
 - i. Published findings on research ethics and translational science ethics (Appendix #3).

3. Year 3 Plans

- a. Development of research on research ethics:
 - i. Roll out surveys on research misconduct; analyze data collected.
- b. Apply research findings on research ethics to improve C/T research:
 - i. Develop guidelines, policies, and training materials based on research findings.
 - ii. Publish data for CTSA-wide use.

D. MAJOR ACCOMPLISHMENTS

- Prepared an analysis of current research consent and governance at the University of Miami School of Medicine and provided recommendations on feasibility and risk of alternate models to senior leadership
- Collaboration with the University of Florida CTSI: We have linked the two CTSI ethics units to contribute to work on issues in consent and secondary data use, have exchanged ethics program faculty for talks and workshops and remain in close contact exploring ways for the 20-year UF-UM ethics collaboration to be a resource for other statewide biomedical research projects.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, we participated in consortium activities and meetings, as well as working intensively with partner CTSA Institution University of Florida.

Miami CTSI Novel Clinical & Translational Methods, Technologies & Resources Program

Data and metrics for this program can be found in Appendix #4

- A. PERSONNEL** **Leadership:** Norma Kenyon, PhD, Director; Jeffery Vance, MD, PhD, Co-Director; Herman Cheung, PhD, Co-Director
Other Personnel: Tamara Levine, Director, Business Operations for U Innovation; Andrew Vinard, Director of Biotechnology Resources, Miller School of Medicine

B. GOALS

The goal of this program is to provide a comprehensive platform that fosters an interdisciplinary academic environment in which researchers are inspired and fully supported in their efforts to develop new lines of investigation and novel scientific methods.

C. PROGRESS AND PLANS

AIM 1: Facilitate access to and utilization of core resources/technologies; identify need for new cores/sun-setting outdated cores as rationale and support for new technologies becomes evident.

1. Year 2 Plan
 - a. Creating wide-spread knowledge of, and user-friendly access to, available core and shared resources
 - b. Hold CaneSearch, Shared Resources Fair (Feb 2014)
2. Year 2 Progress
 - a. Several activities have been ongoing in relation to core and shared resources, including the annual Shared Resources Fair, held in February 2014 in conjunction with CaneSearch. The top project/poster received \$2,000 worth of vouchers for core utilization. (Appendix #4)
 - b. A survey asking questions about core services, including quality, efficiency and technical support, was sent out to faculty, staff and administrators and the data is being collated to improve services.
 - c. Establishing a working group composed of representatives from across UM to review and discuss a draft policy for management of core and shared resources; the policy has already been vetted with core administrators and they will remain involved as feedback/revisions are obtained from the working group.
 - d. Andrew Vinard has worked extensively with leadership to identify an optimal e-platform for management of core and shared resources and we are nearing consensus.
3. Year 3 Plans
 - a. Research cores across UM (quality control practices, business plans and practices, online billing, tracking of productivity) harmonized.
 - i. Implementation of policy/protocol at Medical School and other schools.
 - b. Common e-platform to request/gain access to core services established.
 - c. Plan date and theme for Annual Shared Resources Fair as part of CaneSearch.

AIM 2: Accelerate the development of novel clinical and translational methods by promoting interdisciplinarity.

1. Year 2 Plan
 - a. CaneSearch, Poster Session and Collaborative Research and Exchange Forum (Feb 2014)
 - b. Hold Innovation and Technology Showcase (Nov 2013)
 - c. Issue new Wallace H. Coulter Center for Translational Research RFP in June 2013

Year 2 Changes

Jennifer McCafferty, PhD, Assistant Vice Provost for Research, University of Miami was added to the Novel Methods Program as a Co-Director. Given her university-wide role, her primary focus is fostering multidisciplinary collaborations between the medical school and other UM schools.

2. Year 2 Progress
 - a. CaneSearch was held in February 2014 with a broad theme of neuroscience for the poster session and a specific focus on the neuroscience of HIV and drug abuse for the Collaborative Research Exchange Forum. Dr. Nora Volkow of the National Institute for Drug Abuse was a featured speaker, and Dr. Jose Szapocznik, UM CTSI PI, as well as scientists from Florida International University (Dr. Madhavan Nair) and the University of Florida (Dr. Habibeh Khoshbouei) were also speakers. Several hundred people

attended the day-long event. An additional activity this year was a panel discussion led by Dr. Jason Campagna of The Medicines Company. CaneSearch concluded with a cocktail reception where attendees and speakers were able to mingle, network and discuss future collaborations. Dr. Nair has already returned to UM to give an additional seminar and to meet with Dr. Kenyon and one of our veterinarians, Dr. Daniel Rothen, to discuss testing of a novel nanotechnology platform for delivery of HIV therapeutic agents across the blood brain barrier in a nonhuman primate model. An animal care and use protocol and research agreement are in process. Should this technology be successful, there are additional applications for targeting of specific tissues in the setting of inflammation related to transplantation, autoimmunity and other conditions, as was discussed in detail with Dr. Nair. Testing of his novel technology in nonhuman primates is a key step in the translation of his research to patients, and UM is well equipped to collaborate in this initiative.

- b. The Coulter Center, in collaboration with the CTSI, funded 6 new projects this year, spanning cancer, schizophrenia and glaucoma. Selected for their commercial potential, projects are supported with both funding and a team that engages them in the “Coulter Process”. This process involves delineation of the “killer” experiment that will convince potential business partners that a technology has merit, pairing of researchers with clinicians, business people and their tech transfer liaison. To date, 16/21 UM start-ups formed since 2006 have received Coulter Center support and have raised over 60M of follow on funding. Without commercialization, novel therapies generated at academic centers may only reach a few individuals. The goal of the Coulter Center is to take UM’s most promising technology and guide commercialization to ultimately reach the greatest number of people.
 - c. Held Innovation and Technology Showcase in November 2013 in conjunction with celebration of Wallace H. Coulter’s 100th birthday
 - d. U Innovation partnered with the CTSI to host a lunch and learn session on the impact of the America Invents Act on patenting, held in the Life Science and Technology Park; additional seminars are upcoming (on the medical and the Gables campuses) on April 1.
3. Year 3 Plans
- a. Increase interdisciplinary activities and grant submissions.
 - i. Plan CREF as part of third annual CaneSearch
 - ii. Review impact and determine funding for FY15 Coulter Center grants
 - b. Discussion of survey, engagement of faculty, and planning for third annual CaneSearch (annual)
 - c. Continue Seminar Series that highlights innovation and commercialization of discoveries implemented.

AIM 3: Provide a mechanism to link C/T studies with commercial potential to technology transfer resources that assist with patenting processes and identifying potential corporate partners.

1. Year 2 Plan

- a. Expanded outreach to stimulate innovation and develop IP across the University of Miami
- b. Work with the Office of Advancement to identify philanthropic dollars for innovation initiatives
- c. Hire new Director for technology transfer, Coulter Project Director, and Entrepreneur in Residence

2. Year 2 Progress

- a. In this grant year, U Innovation has hired a Technology Transfer Director, Coulter Center Project Director (CPD), and an Entrepreneur in Residence (EIR). Our new OTT Director, Mr. Jim O’Connell, joined UM with significant business expertise; Jim worked at Stryker and 2 start-ups in the past, was the CPD at U Michigan and assisted them in getting their 20M endowment from the Coulter Foundation; he led the Ventures/Start-Up group in tech transfer at U Michigan. Melda Uzbil, our CPD, was previously the CPD at Duke, responsible for work that led to a 20M endowment from the Coulter Foundation and continues to work with the state of Michigan to support entrepreneurial endeavors. Melda has reorganized the Coulter Center activities to fully capture all aspects of the Coulter process. Bob Williamson, our first med school EIR is a successful businessman who is part of New World Angels. He has worked with U Innovation to pair specific technologies, including a novel anti-inflammatory agent, a mobile healthcare app, a paradigm shifting technology for cancer research/drug discovery/therapy, a novel anesthetic and others, with successful business people (who become voluntary EIRs) who can support business plan development and serve as CEOs to start-ups. With these key hires, U Innovation (OTT, Coulter Center) continues its transformation into a group that proactively supports commercialization of UM inventions. We are actively working with companies to

facilitate licensing, sponsored research agreements and discussions of new models for interaction. Active interviewing has been ongoing to hire two new licensing associates and 2 offers are in process.

- b. In FY13, UM had 19 license agreements and 8 start-ups, a record, and we are on track for 30 license agreements and 10 start-ups in this FY. Several of our start-ups have been approved for and some have already received funding from the Florida Institute for the Commercialization of Public Research.
- c. We initiated an exercise on the "Innovation Ecosystem" (Year 1) at the University with our partners at Wexford (they built and manage our life science park); Tom Osha, head of innovation for Wexford (Wexford has 10 research parks across the country) met with all but one Dean, research deans, entrepreneurial faculty, and leadership in the Office of the Provost to discuss perspectives on innovation and entrepreneurship at UM. There was a great deal of enthusiasm and Dr. Kenyon and Mr. Osha followed up in October of 2013 with all participants to review the findings. One proposal that arose from this was to have a strategic retreat on innovation with Deans and their research deans; this activity is targeted for grant year 3.
- d. U Innovation worked with Business School Dean Gene Anderson to establish a course that was offered and run for the first time in fall 2013; 4 MBA students worked to analyze our mobile health care technology. Meetings with Susannah Alvarez in the Business School has led to an agreement to have undergraduates in her 2015 spring entrepreneurship class work with OTT to evaluate invention disclosures. We have also identified and are working with a School of Communications student on website development and with 2 law students to work on MTAs, CDAs and our tech database (KDD).

3. Year 3 Plans

- a. Develop and implement mechanism to track C/T outcomes related to innovation office.
 - i. Continue infrastructure update; provide metrics on a quarterly basis to Chairs and Deans
- b. Conduct other Innovation/Entrepreneurship Activities.
 - i. Educational outreach to departments and centers, including development of website content
 - ii. Develop dashboard for investigators, chairs and deans to assess IP status
- c. Develop centralized corporate repository.

Year 3 Planned Changes

A transformative change is being made to this Program through the addition of Alessia Fornoni, MD (Year 1 Pilot Awardee) as Program Co-Director. She has unique expertise in creating innovative academia-industry partnerships and will focus mentoring investigators on such. She will play a critical role in putting together a Scientific Advisory Board (SAB) composed of industry representatives to provide guidance on building industry relationships, evaluate and advise Novel Methods mentees and projects.

AIM 4 Plan: Track development of novel methods & technologies resulting from CTSI activities.

1. Year 2 Plan

- a. Monitoring clear evidence of novel, interdisciplinary translational research projects (increased grants, contracts and publications) and/or increased licenses for technology
- b. Launch a University-wide initiative to promote new culture and new rules for promotion and tenure in regard to team science
- c. Projects chosen and supported by new business school course
- d. Tracking, monitoring and coaching of newly funded Coulter-funded projects

2. Year 2 Progress

- a. Tracking system for intellectual property activities being revamped and built up; Coulter Center quarterly meetings in progress for all projects.

3. Year 3 Plans

- a. Develop and implement program tracking system and dashboard, provide metrics to Chairs and Deans on a quarterly basis; provide data to investigators

D. MAJOR ACCOMPLISHMENTS

New collaboration that developed out of CREF in February 2014: Testing of a novel nanotechnology platform for delivery of HIV therapeutic agents across the blood brain barrier in a nonhuman primate model.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, we participated in consortium activities and meetings, as well as working with partner CTSA institutions.

Miami CTSI BioResource Program

A. PERSONNEL **Leadership:** Richard Cote MD, Director; Carmen Gomez MD, Co-Director; Jacob McCauley PhD, Co- Director; Phil Chen MD PhD, Co-Director; Joseph Zeitouni MD, Co-Director

B. GOALS

The University of Miami (UM) has a number of well-established biospecimen collections that contain a wide array of samples from diverse patient populations in South Florida. These collections represent the rapidly growing Hispanic/Latino portion of the U.S. demography. There are 12 major collections across campus housing over 400,000 biospecimens, including one of the largest collections of blood and DNA in the country at the John P. Hussman Institute for Human Genomics (HIHG). The CTSI BioResource at UM is designed to build upon the strengths of these actively used resources to further develop a scalable infrastructure that supports research programs across the medical school. The principal objective of this program is to facilitate access to the necessary raw materials, namely a means to procure human samples and associated annotations and data that will serve as a crucial engine for translational research for CTSI investigators at the University and investigators across the CTSA consortium.

C. PROGRESS AND PLANS

AIM 1: Establish a Governance structure and a user advisory group for the BioResource Program. Develop and implement SOPs for consent, privacy, collection, procurement, processing, storage and distribution of samples.

1. Year 2 Plan

a. Develop and implement SOPs for consent, privacy, collection, procurement, processing, storage and distribution of samples.

2. Year 2 Progress

a. Development and implementation of governance structure and required policies for the BioResource Program.

i. SOPs implemented for the Sylvester Cancer Center Tissue Bank to serve as the standard for the BioResource Program: Participant consent, IRB and privacy protocols; Collections and procurement of samples; Data storage and transfer

ii. Discussions with Ethics program on conducting a common informed consent process

iii. Ongoing discussions with Biomedical Informatics Program for the development of URIDE and incorporation of BioResource Program specimen data

iv. Procurement of Tissue MicroArray

b. Development of a User Advisory Group.

i. Established pilot model for a User Advisory Group and Biospecimen Adjudication Committee within the Sylvester Cancer Center Tissue Bank Core Facility (TBCF).

3. Year 3 Plans

a. Development and implementation of governance structure and required policies for the BioResource Program

i. Develop SOPs for data storage and transfer into URIDE

ii. Implementation of trusted broker mechanism for utilization of data associated with BioResource samples

iii. Incorporation of all pathology archival formalin-fixed paraffin embedded samples that have exceeded clinical statutory storage requirements into the BioResource repository

b. Develop an active and engaged User Advisory Group.

i. Regular surveys of the Research Community and other CTSI programs to meet the needs of our UM investigators and research community at large

ii. Enlist the User Advisory Group in the development of Tissue MicroArray samples for specific investigator projects

- c. New BioResource Initiatives being created by the Sylvester Cancer Center, to be brought into CTSI infrastructure
 - i. Establish live cell culture banking program (Tan Ince, MD PhD)
 - ii. Establish xenograft tissue banking program (Noriyuki Kasahara, MD PhD)

AIM 2: Establish customer profiles and a sustainable business plan for the BioResource Program.

1. Year 2 Plan

- a. Develop an initial "Virtual Storefront" tool for investigators across the UM medical campus to query de-identified information on currently collected biospecimens.
- b. Secure additional UM investigator contracts and external funding sources for BioResource sustainability efforts.

2. Year 2 Progress

- a. Characterization of current demand and utilization of samples across UM.
 - i. Completed in-depth characterization of users of samples within UM.
 - ii. Completed analysis of active IRB studies using biospecimens at UM.
 - iii. Identified and engaged key investigators for medium to large scale sample collections.
- b. Harmonization of existing services and costs across Centers within UM.
 - i. Initiated integration of sample acquisition and tracking between HIHG and Cancer Center TBCF.
 - ii. Created a new system in which the TBCF now stores biospecimens at the HIHG.
- c. High profile/use cases identified as "initial champions" of the BioResource Program.
 - i. Champions identified and approached to understand their needs; needs being evaluated by program leadership to set priorities and goals. The champions are as follows:
 - Tan Ince, MD, PhD, Associate Professor of Pathology
 - Joyce Slingerland, MD, PhD, Professor of Medicine; Director, Braman Family Breast Cancer Institute
 - Marc Lippman, MD, Professor of Medicine; Deputy Director, Sylvester Cancer Center
 - Richard Cote, MD, Chair of Department of Pathology
 - Ricardo Komotar, MD, Asst. Professor of Neurological Surgery; Director of Neuro-Oncology
 - Anthony Capobianco, PhD, Professor of Surgery
 - Izidore Lossos, MD, Professor of Medicine
 - Deborah Mash, PhD, Professor of Neurology; UM Brain Endowment Bank

3. Year 3 Plans

- a. Build on current demand and utilization of samples across UM.
 - i. Increase utilization of existing specimens via implementation of specimen search functionality in URIDE.
 - ii. Increase number of users for the BioResource, according to understanding of current demand.
- b. Harmonize existing services and costs across Centers within UM.
 - i. Increase tracking of services and costs to ensure utilization and sustainability.
 - ii. Review staffing for participant consenting in order to maximize efficiency and reduce cost.
- c. Expand and refine "champions" initiative.
 - i. Continually assess the needs and requirements of key investigators.
 - ii. Incorporate feedback from investigators to strengthen and grow the BioResource Program.
 - iii. Engage additional investigators to help demonstrate added value of CTSI to existing related UM resources.

AIM 3: Development and initiation of a plan for a BioResource informatics infrastructure.

1. Year 2 Plan

- a. Incorporate the expertise of Dr. Joseph Zeitouni, Associate Director of Pathology Informatics, who beginning in Year 2 will Co-Chair the IT Informatics Subcommittee of this Component. Dr. Zeitouni will assist Dr. Chen with the collaborative creation and design of the data systems infrastructure for the BioResource Program.

2. Year 2 Progress

- a. Integration of BioResource Program data systems into the data environment of the CTSI Biomedical Informatics Program.
 - i. Developed pilot database (caTissue) to allow users to query for de-identified longitudinal clinical and sample data
 - ii. TBCF data provided to CTSI Biomedical Informatics Program for incorporation into the URIDE Phase 1 project
- b. Standardization of protocols for clinical and pathological tissue annotations/structured data fields
 - i. REDCap templates for patient demographics being designed and standardized by the Sylvester Cancer Center.
 - ii. A new add-on module called mTuitive (a synoptic reporting solution) to Sunquest CoPathPlus will provide structured pathology data capture.
- c. Development of common tracking system for samples and sample attributes.
 - i. Developed coordinated storage system through searchable database.
- d. Harmonization of existing and future storage systems for samples.
 - i. Integrated multiple data platforms as well as support for future systems.
- e. Introduction of clinical patient biospecimen test results into URIDE

3. Year 3 Plans

- a. Integration of BioResource Program data systems into the data environment of the CTSI Biomedical Informatics Program.
 - i. Design and incorporate a user interface to search for, and summarize structured clinical lab data in URIDE.
 - ii. Flag cohorts of patients in URIDE with archived pathology specimens and other banked biospecimens.
- b. Develop common tracking system for samples and sample attributes.
 - i. Establish a common tracking system for sample attributes with a transfer of structured data into URIDE.
 - ii. Explore ways to incorporate data gathered in REDCap forms as additional specimen annotations/attributes for existing and future collections in the BioResource Program.
- c. Harmonize pre-existing sample databases into single system.
 - i. Integration of biospecimen data from Nautilus, caTissue and potentially REDCap into URIDE.
- d. Harmonize existing and future storage systems for samples.
 - i. Establish a common tracking system for sample storage using Nautilus.

D. MAJOR ACCOMPLISHMENTS

- SOPs implemented for the Sylvester Cancer Center Tissue Bank to serve as the standard for the BioResource Program: Participant consent, IRB and privacy protocols; Collections and procurement of samples; Data storage and transfer
- Initial integration of BioResource Program data systems into the data environment of the CTSI Biomedical Informatics Program through pilot database (caTissue) to allow users to query for de-identified longitudinal clinical and sample data

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, we participated in consortium teleconferences.

Miami CTSI Pilot & Collaborative Translational & Clinical Studies Program

Data and metrics for this program can be found in Appendix #5

A. PERSONNEL **Leadership:** Michael Antoni, PhD, Director; Vinata Lokeshwar, PhD, Director
 Other Personnel: Patricia Avissar, Research Navigator

B. GOALS

The Pilot & Collaborative Translational & Clinical Studies Program brings together under a single administrative consolidated platform, a wide variety of highly specialized pilot programs that are already established at the University and will develop and manage a diversified portfolio of innovative CTSI-funded pilot studies. All these activities will yield new C/T studies, new partnerships and new opportunities for external funding.

C. PROGRESS AND PLANS

AIM 1: Integrate existing pilot programs under one umbrella: “Federation Umbrella.”

1. Year 2 Plan

- a. Unify UM-based funding sources under “Federation Umbrella” to transform silo-based research into transdisciplinary research in sync with culturalized health topics that serve our community.
- b. Unify the application processes to leverage, supplement, or exchange meritorious applications.
- c. Work with University-based IT resources, CTSI Biomedical Informatics and other stakeholders in choosing a platform to automate the processes of the Pilot and Translational Studies Program.
- d. Reach out to Pilot Programs of the CTSA Consortium to enhance the design of the Federation.
- e. Establish “Success Metrics” with Evaluation Program to monitor the Federation progress.

Year 2 Changes

Federation partners voted to reallocate CTSI supplemental funds to other pilot mechanisms to compensate reviewers in the Reviewer Pool for university-wide core services or travel to scientific meetings.

2. Year 2 Progress

- a. System-wide “Federation Umbrella for Pilot Research Programs” implemented.
 - i. Developed a plan with UM Pilot Program Leaders for furthering interactions among the Federation stakeholders and the implementation of the federation
 - ii. Agreement on common pilot application form, plans for launching on-line version, and a unified plan to form a pool of reviewers to review all federation grants
- b. Application format and process, review criteria and process, have been established.
 - i. Common pilot application form created following the NIH R21 format. Each Pilot mechanism (e.g. Scientific Advisory Committee, Center for AIDS Research, Sylvester Cancer Center) can customize the Common Form with their specific requirements.
 - ii. Common review criteria based on the NIH review guidelines have been agreed upon.
 - iii. Electronically-based system for pilot proposal solicitation and application for use by pilot/collaborative programs was completed:
 - CTSI pilot application is automated and is currently operational with online submission.
 - CFAR is using the electronic application system for its upcoming award cycle (March 2014).
 - BioNIUM (a newly-recruited Pilot mechanism) is planning using the system for launching their upcoming cycle (RFA expected in April 2014).
- c. Centralized pool of reviewers for UM pilot/collaborative programs is being assembled.
 - i. Federation Pilot Program Leaders agreed to sign on to a letter (Appendix #5) addressed to Department Chairs to recruit qualified and experienced reviewers for pilot applications.

3. Year 3 Plans

- a. Implement system-wide “Federation Umbrella for Pilot Research Programs.”
 - i. Formally implement Federation
 - ii. Launch Common application form as on-line format

- iii. Form initial Pool of Reviewers to review all federation grant proposals
- b. Harmonize application format and process, review criteria and process, award process and template, evaluation, and marketing/outreach.
 - i. Apply federation review process in all rounds of federation applications this year
 - ii. Collect data on satisfaction with review process
 - iii. Tabulate highly scored CTSI applications shared among federation partners for funding consideration
 - iv. Use UCSF-RAP format as a model for marketing and outreach platform to communicate all UM wide pilot grant activities.
- c. Promote use of electronically-based system for pilot proposal solicitation, application, and review (goal of usage by 75% of pilot/collaborative programs).
 - i. Collect data on use of electronic/on-line application system for Federation Pilots.
- d. Implement centralized pool of reviewers for UM pilot/collaborative programs (Federation).
 - i. Metrics: % of Pilot Programs using pool of reviewers; number of reviewers entering the Pool of Reviewers from chairman letters versus other sources
 - ii. Roll out the UMSOM-Grant Review Group formally
 - iii. Hold initial networking/award ceremony event for Federation members and UMSOM-Grant Review Group.

AIM 2: Enrich existing Pilot and Collaborative Funding Programs.

1. Year 2 Plan

- a. Work with and through pilot programs to strengthen their interdisciplinarity to be consistent with CTSI theme of culturalized health sciences.
- b. Work with Research Education Program to enhance the mentorship and collaboration initiatives in place.

2. Year 2 Progress

- a. Process in place to ensure that existing CTSI services are made available to Federation pilot awardees.
 - i. CTSI resources/core service credits made available to Federation members to complement the funded pilot projects.
- b. Program in place to ensure that all Federation awardees have career and C/T mentors.
 - i. Supported additional mentorship relationships for awardees.
- c. Increased inter-disciplinarity in Federation-funded studies with supplementary funding.
 - i. The Federation voted to utilize CTSI supplemental funds to compensate the reviewer pool.

3. Year 3 Plans

- a. Process in place to ensure that existing CTSI services are made available to Federation pilot awardees.
 - i. Communicate to Pilot Federation the availability of CTSI resources for their grant awardees.
 - ii. CTSI Pilot Directors will present this initiative in the meetings of individual Pilot Federation partners.
 - iii. Metrics: CTSI services used by Federation members; impact of CTSI services used.
- b. Program in place to ensure that all Federation awardees have career and C/T mentors.
 - i. Establish a process for tracking the number of mentor/mentee pairings among Federation pilot awardees
 - ii. Metrics: Collaborations created between Federation pilot awardees and established investigators.
- c. Increase inter-disciplinarity in Federation-funded studies with supplementary funding.
 - i. Initiative to providing supplement funds to other pilot mechanisms was modified based on the needs/recommendations of Federation partners. The funds allocated will be used to compensate the reviewers in the Reviewer Pool for university-wide core services or travel to scientific meetings.
 - ii. Develop menu of non-CTSI resources and FAQs
 - iii. Metrics: Core services used/scientific meetings attended, scholarly output.

AIM 3: Support talented investigators/projects important to the mission of the CTSI.

1. Year 2 Plan

- a. Refine RFAs to emphasize priority/focus areas in all communications.
- b. Monitor the progress of funded projects using metrics established in AIM 1.
 - i. Grant applications / funding, patents, peer-reviewed publications, conference presentations.
 - ii. Track project qualities: Transdisciplinarity, culturalized health, community relevance. Investigator qualities: Level of training; use of CTSI resources and brokered mentorship.
 - iii. Team Science: Formation of new teams conducting research beneficial to our community.

2. Year 2 Progress

- a. Provision of CTSI-focused pilot awards; mentoring and guidance provided to awardees.
 - i. Completed First Round of Pilot Studies and Service Credits Awards (Jan 2013-2014)
 - ii. Second pilot RFA released on November 8th, 2013 (Appendix #5).
 - iii. Brokered new Mentorships for Awardees.
 - iv. Second progress report for YR1 pilot awardees was held on November 21, 2013.
 - v. Reviewed mentoring of awardees and set up meetings with the applicant and the mentors to optimize the awardees' success.
- b. Scholarly productivity of awardees linked to award (e.g., peer reviewed publications, grant application, extramural support, patents, collaborations) (Appendix #5)
 - i. Monitoring of Grant Review Protocols and Awarded Projects.
 - ii. Establish & Track Short and Long-term "Success Metrics".

3. Year 3 Plans

- a. Provision of CTSI-focused pilot awards; mentoring and guidance provided to awardees.
 - i. Redesign RFA to reflect more awards of smaller amount
 - ii. Encourage applications from investigators who have received favorable review from extramural funding agencies but missed the pay line.
 - iii. Encourage multi-investigator applications which may lead to Team Science projects. The investigators could be within UM or state wide (One Florida).
 - iv. Metrics: CTSI Pilot award process measures, Pilot reviewer activities, Reviewer Satisfaction Survey, Pilot applicants and awardee characteristics, Applicant Satisfaction with Review process, mentoring relationship measures.
- b. Scholarly productivity of awardees linked to award (e.g., peer reviewed publications, grant application, extramural support, patents)
 - i. Monitoring CTSI Pilot Award productivity metrics

D. MAJOR ACCOMPLISHMENTS

- System-wide "Federation Umbrella for Pilot Research Programs" implemented, Federation Pilot Program Leaders agreed to sign on to a letter (Appendix #5) addressed to Department Chairs to recruit qualified and experienced reviewers for pilot applications.
- Electronically-based system for pilot proposal solicitation and application for use by pilot/collaborative programs was completed:

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

We did not participate in any CTSA consortium activities in Year 2.

Miami CTSI Study Design and Biostatistics Program

Data and metrics for this program can be found in Appendix #6

A. PERSONNEL **Leadership:** Shari Messinger Cayetano, ME, PhD, Director; J. Sunil Rao, PhD, Director

B. GOALS

The goal of this Program is to lead, advise, educate and train the next generation of clinical/translational (C/T) researchers in the design and analysis of their studies.

C. PROGRESS AND PLANS

Overall Year 2 Changes: During the course of the year, Co-Director C. Hendricks Brown, PhD, left the University of Miami. Drs. Shari Messinger Cayetano and J. Sunil Rao maintain co-directorship of the program.

AIM 1: Establish University-wide Center for Statistical Sciences.

1. Year 2 Plan

a. Begin planning for Center for Statistical Sciences, which entails putting forth an appropriate business plan and getting formal approval by the Miller School of Medicine Council, Faculty Senate and sign off by the Provost and President of the University.

2. Year 2 Progress

a. Implement University approved Center for Statistical Sciences.

i. Began developing a business model for the Center for Statistical Sciences to obtain Faculty Senate and University approval

b. Develop Interdisciplinary research groups on specific statistical/research design issues.

i. An initial academic CREF is being created between the School of Medicine and the School of Engineering to look at issues related to Big Data Analysis.

3. Year 3 Plans

a. Implement University approved Center for Statistical Sciences.

i. Implement Center

b. Implement Workshops on statistical sciences through the Center.

i. Develop Joint workshop with UF.

c. Develop Center's Visiting Scholars Program, provided funding is available.

i. Invite one scholar.

d. Develop Interdisciplinary research groups on specific statistical/research design issues.

i. Decision theory research group with Business School

AIM 2: Provide research design and biostatistics support to C/T investigators through the Biostatistics Collaboration and Consulting Core.

1. Year 2 Plan

a. The Core will continue to provide research design and biostatistics support, provided through office hours, collaborative support, dissemination of findings through manuscript preparation, and in the support of pilot projects and other Miami CTSI funding mechanisms.

b. Core resources will be prioritized towards culturalized health sciences and health disparities research

c. Biostatistics Core faculty and staff will engage in activities of the proposed Center, fostering communication and increasing opportunities for methods research.

d. Core faculty and staff will also engage in educational opportunities offered through the proposed Center.

e. Productivity can be evaluated by consultations provided to C/T investigators and number of projects supported that are submitted for publication in top tier journals or for extramural funding.

2. Year 2 Progress

- a. Collaborative and consulting activities provided. (Appendix #6)
 - i. Provision of research design and biostatistics support to C/T investigators through the Biostatistics Collaboration and Consulting Core.
 - ii. Priority given to projects on health disparities and culturalized health sciences.
3. Year 3 Plans
- a. Provide collaborative and consulting activities.
 - i. Continue to provide research design and biostatistics support to C/T investigators through the Biostatistics Collaboration and Consulting Core.
 - ii. Interface with other CTSI resources such as Bioinformatics in order to facilitate investigator initiated research.

AIM 3: Develop new biostatistical methods to move translational research forward.

1. Year 2 Plan
- a. Provide Biostatistical novel methods developmental awards
 - b. We plan to produce a paper on Scientific Equity that maps out design requirements for randomized trials of interventions and strategies for synthesizing findings from the literature related to health disparities.
 - c. Together with our collaborators, we plan to submit an NIH application to develop the biostatistical and psychometric methodology for extending computerized adaptive testing to minority populations.
2. Year 2 Progress
- a. Development of new Biostatistical methods that facilitate analysis and assessment in C/T research.
 - i. Multiple statistical methodology papers published and multiple presentations given nationally and internationally. (Rao: two papers published and five talks given; Ishwaran: one paper published and one talk given) (Appendix #6)
 - ii. Four Biostatistics PhD students currently involved in statistical methodology development.
 - iii. Two new NSF grant submissions submitted on statistical methods development (Rao (1); Ishwaran (1))
 - b. Development of software modules for new biostatistical tools used to move C/T research forward.
 - i. Software module on random survival forests developed (RSF) as a partial product of pilot funding above.
 - c. In Year 2, two \$10,000 Developmental Awards were given to faculty in the School of Law and Department of Psychology in the College of Arts and Science.
3. Year 3 Plans
- a. Development of new Biostatistical methods that facilitate analysis and assessment in C/T research.
 - i. Develop new areas of research methodology pertaining to Patient Centered Outcomes research.
 - ii. Broaden areas of research expertise through hiring of additional faculty.
 - iii. Write statistical methods papers with students as co-authors.
 - b. Biostatistical Developmental Awards will become a fully participating member of the Federation of Pilot Programs.
 - i. Formalize pilot program, release competitive RFA, and increase visibility.

AIM 4: Provide educational programs to train the next generation of clinical researchers and biostatistical scientists to improve the quality and quantity of research.

1. Year 2 Plan
- a. We will look to formalize quantitative health disparities research and education by producing research papers, developing new software modules for wider usage of methods that we will develop and developing new training programs relating to issues in quantitative health disparities research.
 - b. We will begin building our curriculum based on our plans in the already submitted T32 training grant application in quantitative epidemiology and biostatistics with a slant towards quantitative health disparities.

2. Year 2 Progress

- a. Biostatistical clinics and roundtables for UM faculty, students, researchers implemented - ongoing. (Appendix #6)
- b. Workshops on statistical sciences developed and implemented – ongoing basis. (Appendix #6)
- c. Academic degree programs in biostatistics developed and implemented (M.S., Ph.D.).
 - i. Ph.D. program in Biostatistics have 6 students completing their first year of studies, and 3 additional for Fall 2014
- d. New courses in bio-statistics implemented.
 - i. New course on the Statistical Analysis of Clinical Trials data developed (Fall 2013 semester – Messinger, Quintana and Rao instructors).
 - ii. New course in Statistical Consulting (Summer, 2013)
- e. A process was developed for the creation of an undergraduate degree in biostatistics.
- f. Submit a T32 application in biostatistics.
 - i. Submitted a T32 training grant application in quantitative epidemiology and biostatistics with a slant towards quantitative health disparities.
- g. Development of MD/MS program in computational medicine.
 - i. Initial discussions have happened and a template curriculum is being developed.

3. Year 3 Plans

- a. Biostatistical clinics and roundtables for UM faculty, students, researchers - ongoing.
 - i. Continue to provide clinics and roundtables; increase topics offered.
- b. Expand Academic degree programs in biostatistics (M.S., Ph.D.).
 - i. Revamp MS program in Biostatistics to a 1-year degree.
 - ii. Enroll 3-5 additional Ph.D. students.
- c. Implement new courses in bio-statistics.
 - i. Introduce 3 new courses (probability theory, Bayes, advanced computing, and high dimensional data analysis)
- d. Develop and implement MD/MS program in computational medicine.
 - i. Continue development of program.
- e. Continuing Education of faculty.
 - i. Professional development workshop offered to faculty

D. MAJOR ACCOMPLISHMENTS

- Three Developmental Awards given to faculty on other UM campuses
- T32 training grant application in quantitative epidemiology and biostatistics with a slant towards quantitative health disparities was submitted

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, Dr. Shari Messinger was a voting member of BERD KFC and currently participates in two working groups:

- a. Promotion and Tenure working group
- b. Best Practices for Statistical Consulting working group

Miami CTSI Regulatory Knowledge and Support Program

Data and metrics for this program can be found in Appendix #7

A. PERSONNEL **Leadership:** Jonelle E. Wright, PhD, Director; Margaret Fischl, MD, Director
Other Personnel: Sylvia Morales, Associate Research Subject Advocate; TBA, Research Subject Advocate; TBA, Regulatory Quality Improvement Specialist

B. GOALS

A centralized resource of regulatory knowledge and support is essential for facilitating clinical and translational (C/T) research, and for assuring consistent standards in the protection of human subjects and adherence to responsible conduct of research and protocol integrity standards. The Regulatory Knowledge and Support Program will provide leadership and individualized investigator-focused resources and guidance early in the planning of clinical protocols and throughout study implementation.

C. PROGRESS AND PLANS

AIM 1: Enhance clinical research infrastructure to advance human protections, Responsible Conduct of Research (RCR) and human research protocol integrity.

1. Year 2 Plan

- a. Finalize hires for regulatory staff.
- b. Initiate process improvement activities as appropriate.
 - i. Keep abreast of and record CTSA Consortium resources appropriate for adoption at UM and introduce new developments from CTSA Consortium to appropriate UM stakeholders.
 - ii. Continue work on Career Ladder and job descriptions.
 - iii. Continue work on Clinical Research Coordinator training curriculum.
- c. Continue work on Trusted Governance System and clinical consent for secondary (research)
- d. Continue to provide human subjects' safety, DSMP, and protocol quality improvement consultation.

2. Year 2 Progress

- a. Associate Research Subject Advocate has been hired and in the process of training.
- b. Process improvement mechanism for RCR, human protections, & protocol integrity established and ongoing.
 - i. Advisory Panel membership finalized and committee operational. (Appendix #7)
 - ii. IRB Share initiation work completed, IRB contract signed, promoting resource to investigators (ongoing).
 - iii. UM adoption of CTSA consortium tool - ResearchMatch.
 - iv. Strong working relationship with Clinical Research Operations and Regulatory Support (CROSS) office, collaborations initiated in Clinical Ladder and Clinical Research Center Training efforts
 - v. Clinical Research Coordinator Career Ladder with correlating job description structure developed and currently being implemented by Human Resources
- c. Developed educational resources, tools/templates for protocol adherence (including protocol integrity & human protection tools). (Appendix #7)
 - i. IRB Grand Rounds started (Oct 2013) and continuing offerings
 - ii. IND Primer finalized and approved, posted on CTSI website (Appendix #7)
 - iii. Decision tree for requirements for protection of human subjects in clinical research for posting on CTSI website (in process)
 - iv. 3 IRB Grand Rounds presented to date (1 CTSI-related (Goodman))
- d. Developed and provided active consult service on RCR, human protections, human research protocol integrity. (Appendix #7)
 - i. Initiation, administration, and promotion of consultation service in CTSI CRC network
 - ii. Program leadership provided consults before hiring of QI personnel

3. Year 3 Plans

- a. Process improvement mechanism for RCR, human protections, & protocol integrity (ongoing).
 - i. Advisory Panel addresses strengths & opportunities and advises on CTSI role in advancing progress in institutional process improvements (ongoing)

- ii. Promote IRB Share to researchers (ongoing)
- iii. Institutional adoption and promotion of ResearchMatch
- iv. Active CTSI promotion of human protections, RCR, & protocol integrity in institutional regulatory support activities in CRORS collaboration (ongoing)
- v. Submit AAHRPP application
- vi. Finalize Clinical Research Coordinator Career Ladder with correlating job description retro-fitted for school-wide implementation
- vii. Regulatory-related content incorporated in 3-part Clinical Research Professionals educational program with Parts 1&2 (i.e. U-Way & CBLs) underway
- b. Develop and make available Educational resources, tools/templates for protocol adherence (including protocol integrity & human protection tools).
 - i. Develop active repository of learning modules on human subject protections, RCR, & protocol integrity.
 - ii. Develop and post CTSI website content on Human subject protections, RCR, & protocol adherence, incorporate in clinical research professionals' educational programs.
 - iii. Develop and submit decision trees & templates for specific components of human subject protections for posting on CTSI website.
 - iv. Regular IRB Grand Rounds (on-going).
- c. Active consult service on RCR, human protections, human research protocol integrity developed & provided.
 - i. Hire and orient CTSI QI Specialist
 - ii. Promote and roll-out consult service
 - iii. CTSI QI Specialist work orchestrated with Associate RSA and CRORS team
 - iv. Operationalize consult service

AIM 2: Provide research participant advocacy; enhance clinical research quality improvement through Data and Safety Monitoring Plan (DSMP) resources.

1. Year 2 Plan
 - a. Continue inventorying UM resources to identify and consolidate best practices/templates for human subjects' safety, DSMP, and adherence to regulatory guidelines.
 - b. Maintain CTSI, Office of Research, Research Education, and Innovative Medicine and CRORS collaboration in building repository of human subjects' safety, DSMP, and regulatory-related tools, templates, and best practices.
 - c. Initiate operations of repository.
2. Year 2 Progress
 - a. Research Subject Advocate and RSA services implemented within the CTSI. (Appendix #7)
 - i. Associate RSA hired and in process of training on new approach to DSMP
 - ii. Introducing concept to Human Subjects Research Office (HSRO) and Alianza program.
 - iii. Currently recruiting RSA
3. Year 3 Plans
 - a. Implement Research Subject Advocate and RSA participant-focused services within the CTSI.
 - i. RSA services rolled out
 - b. Investigator-focused RSA consults for clinical research protocols.
 - i. Hire and orient RSA

AIM 3: Operationalize CTSI Data and Safety Monitoring Plan (DSMP) Resource.

1. Year 2 Plan
 - a. Finalize DSMP framework, template, and tools.
 - b. Hire, orient, and train RSA.
 - c. Start to build operational components of DSMP program.

Year 2 Changes

During the year, Associate Research Subject Advocate Sylvia Morales was hired into the Regulatory Knowledge and Support Program. HSE certification is provided in “HSE for new personnel” section of this report.

2. Year 2 Progress

- a. Establishment of Data and Safety Monitoring Planning resource.
 - i. DSMP protocol service framework structured
- b. Development of protocols for study-specific and research personnel-specific DSMPs.
 - i. Study-specific DSMP template developed
- c. Adoption of DSMP protocols within the CTSI/UM (e.g. buy-in from CRORS & IRB).
 - i. Obtained internal endorsement from medical school Research Cabinet and HSRO leadership
- d. Advice readily available to investigators regarding Data & Safety Monitoring Committee charters.
 - i. Provided consultation for structuring and running a DSMB at Jackson and served as DSMB member.

3. Year 3 Plans

- a. Establish Data and Safety Monitoring Planning resource.
 - i. Develop DSMP decision trees & templates.
 - ii. Initiate CTSI DSMP consult & educational services, CRORS oriented to new services
 - iii. Develop and submit web-based training module for study-specific DSMP
- b. Develop protocols for study-specific and research personnel-specific DSMPs.
 - i. Initiate study-specific DSMP development consult & educational services
 - ii. Expand protocol/process to research personnel-specific DSMP (Year 4)
- c. Adoption of DSMP protocols within the CTSI/UM (e.g. buy-in from CRORS & IRB).
 - i. CTSI-CRORS collaboration in roll-out strategy
- d. Advice readily available to investigators regarding Data & Safety Monitoring Committee charters.
 - i. CTSI-CRORS collaboration in CTSI DSMC/B advisory roll-out strategy.
 - ii. Respective institutional counsels define UF-UM Reciprocal DSMC/B MOU elements, develop procedural steps for institutional approval, & identify liability/protections framework.
 - iii. Pilot UF-UM Reciprocal DSMC/B

D. MAJOR ACCOMPLISHMENTS

- Approval and go-ahead obtained from UF VP for Research and UM Vice Provost for Research, Executive Dean for Research, and Associate Vice Provost for Human Subject Research for UM-UF Reciprocal DSMB arrangement.
- Institutional approval and go-ahead obtained for new job description structure and format for 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 and go-ahead obtained from Institutional leadership for IRBShare, contract signed and operational.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Before reorganization of CTSA Consortium, participated in several CTSA Consortium monthly conference calls: Regulatory Knowledge and Clinical Research Ethics Key Function Committees, and Clinical Research Management and Research Coordinator subgroups.
2. Helping lead Clinical Research Coordinator training curriculum to be aligned with career ladder and job descriptions.
3. Attended CTSA Steering Committee Annual meeting, co-authored slide presentation entitled “Lessons Learned in Advancing Innovation in Education and Training – Clinical Research Professionals Workforce Development”.
4. Member of post-reorganization CTSA subcommittee on CTSA GCP Certification activities led by Dr. Richard Barohn, CTSA PI (Kansas) and NCATS CTSA Steering Committee member.
 5. NIH Special Emphasis Panel/Scientific Review Group 2013/05 ZTR1 CG-1 (01) reviewer assigned CTSA-related applications.

Miami CTSI ¡Alianza! Miami Center for Research Participation and Partnership Program

Data and metrics for this program can be found in Appendix #8

A. PERSONNEL **Leadership:** Matthias Salathe, MD, Director; Tracie Miller, MD, Director; JoNell Potter, ARNP, PhD, Director

Other Personnel: Joanne Krasnoff, PhD, Senior Manager, Research Support

B. GOALS

¡Alianza! is the Miami CTSI equivalent of the Participant and Clinical Interactions Resources component. ¡Alianza! serves as a centralized core that will offer resources, services and knowledge to improve productivity and collaboration across an existing collection of facilities that perform clinical research. This will enable standardization of operating procedures and best clinical practices and will enhance communication across currently disparate research teams so that multidisciplinary, team-based research collaboration can blossom organically.

C. PROGRESS AND PLANS

Overall Year 2 Changes: Previous Program Director Myles Wolf, MD, left the University of Miami. Matthias Salathe, MD, who is also Division Chief of Pulmonary, Critical Care, and Sleep Medicine was appointed as the new Director for the program.

AIM 1: Establish and implement a harmonized network of centralized, affiliated locations for patient-oriented research.

1. Year 2 Plan

- a. Complete and implement universal clinical research standard operating procedures
- b. Develop a certification process for free-standing clinical research facilities within the Network
- c. Relocate the outpatient adult CRC to an integrated hospital-based inpatient-outpatient unit
- d. Increase ¡Alianza! engagement with community based clinical research sites
- e. Continue working with Pathology to implement single requisition for research lab testing
- f. Examine electronic clinical research documentation

2. Year 2 Progress

- a. Developed “Universal” operating procedures across ¡Alianza! sites.
 - i. Created SOP committee (PIs, research unit directors) and subcommittee (study coordinators)
 - ii. Reviewed & collated existing clinical research site SOPs & determined core Universal SOPs topics
 - iii. Finalized and submitted SOP documents (8), accompanying templates (14) and implementation proposal to the School of Medicine’s Executive Dean for Research
- b. Inpatient clinical research infrastructure developed.
 - i. Developed integrated hospital-based inpatient/outpatient research unit at the University of Miami Hospital (UMH) and corresponding operational workflows (admissions, pharmacy, EMR, HIM, materials management, IT)
 - ii. Staff completed hospital required orientation & training
 - iii. Completed visits for two studies July 2013 (pilot open)
 - iv. Began discussions with Jackson Clinical Research Office (float bed, integrated in/out patient unit)
- c. Awareness of ¡Alianza! and its services among clinical researchers established.
 - i. Developed and implemented a survey to clinical research PIs on the UM clinical research infrastructure (evaluation and needs assessment), 100 faculty respondents.
 - ii. Participation in CTSI informational/marketing presentations with all Medical School departments

3. Year 3 Plans

- a. Assist with implementation of “Universal” operating procedures across ¡Alianza! sites.
 - i. SOP implementation, training, and collaboration with the CRORS office as additional universal SOPs are identified
- b. Continue to develop in- and outpatient clinical research infrastructure.
 - i. Transition existing studies to new unit; attract new studies; establish new workflows
 - ii. Assist UMH to implement new workflows to enhance inpatient research studies
- c. Increase presence of Alianza and Alianza services among clinical researchers.

- i. Work with CTSI and other research offices to improve and/or establish greater clinical research efficiency in those areas identified in the survey.

AIM 2: Create a centralized operational core to enhance education, training, competency, career development, and productivity for clinical research professionals.

1. Year 2 Plan

- a. Complete development of and conduct institution-specific clinical research training initiative (with Education and Regulatory components) to include and integrated set of didactic sessions, workshops, and practice mentorship/internships for research support staff
- b. Complete development and beta testing of computer-based learning modules for clinical research coordinator education and training in collaboration with partner CTSA's and the Regulatory KFC (with Education and Regulatory components)
- c. Continue hosting Network of Clinical Research Professional gatherings

2. Year 2 Progress

- a. Active and engaged Network for Clinical Research Professionals (NCRP) has been established. (Appendix #8)
 - i. NCRP bimonthly gathering to provide networking and a portal for communication and dissemination of education/training information (avg. attendance 85/seminar)
 - ii. Developed and administered demographics survey to NCRP (~100 clinical research professionals respondents)
 - Survey results support education/training & career ladder efforts, subsequent seminar topics were chosen and developed based on survey responses.
 - iii. Developed and maintain current NCRP listserv
 - iv. Developed evaluation survey for bimonthly seminars
- b. Development and implementation of training/ educational programs for clinical research professionals.
 - i. Piloted two daylong U-Way Workshops (Sept 2013, Feb 2014; 12 participants & 12 presenters)
 - 100% participants & Presenters evaluated workshop as 'excellent' or 'very good'; detailed comments will guide future workshop implementation
 - ii. Began internal review of drafted CBLs (computer-based learning modules)
 - iii. Discussions with Drs. King and Tiberius on 'how to be a mentor/mentee workshop'
- c. Development of NCRP web content aimed at facilitating clinical research.
 - i. Bimonthly seminar presentations (slides, handouts) posted on NCRP website
 - ii. Drafted pre and post award study workflows (NIH and Industry)
 - iii. Created research workflow subcommittee (study coordinators) to review & discuss draft workflows
- d. Development of Clinical Research Professional Career Ladder in collaboration with Education and Regulatory programs and UM Human Resources.
 - i. Clinical Research Coordinator Career Ladder with correlating job description structure is being developed and in process of approval by Human Resources.

3. Year 3 Plans

- a. Continue activities of Network for Clinical Research Professionals (NCRP).
 - i. Bimonthly NCRP seminars (on-going)
 - ii. Administer and review seminar evaluations (satisfaction, future seminar topics/group needs)
- b. Develop and implement training/ educational programs for clinical research professionals
 - i. Repackage U-Way workshop format to efficiently and effectively disseminate content and experience to ~ 800 clinical research professionals (i.e. web presentations to watch in advance of in-person Q&A)
 - ii. Pilot CBLs to Clinical Research Coordinator workgroup, Clinical Research Unit Directors/Investigators
 - iii. Collaborate with the Clinical Research Operations and Regulatory Support (CRORS) office to draft implementation and follow-up/maintenance plan
 - iv. Establish first Clinical Research unit adequately prepared for mentorship activities
- c. Continue developing NCRP web content aimed at facilitating clinical research.
 - i. Post seminar presentations on NCRP website; complete workflows and post on the NCRP website
- d. Clinical Research Professional Career Ladder in collaboration with Education and Regulatory programs and UM HR developed.
 - i. Finalize career ladder structure with HR and align job descriptions to training requirements

- ii. Develop training required for clinical research professionals to move from on career level to the next.
- iii. Establish expectations for sessions, workshops, and practice mentorship/internships depending on experience

AIM 3: Enhance infrastructure to ensure adherence to the highest ethical and regulatory standards while accelerating the pace of research translation.

1. Year 2 Plan

- a. Complete and implement regulatory-compliant, universal clinical research standard operating guidelines in collaboration with the Regulatory component
- b. Examine Clinical Research Infrastructure Survey data to identify programs and processes that can be improved and develop an action plan
- c. Develop and implement ¡Alianza!-specific Leadership Operations Committee and Scientific Advisory Committee

2. Year 2 Progress

- a. Establish community-based partnerships to offer ¡Alianza! services, education and training
 - i. Began development of plan to engage community-based partners in collaboration with the Community Engagement & Cultural Diversity Program
 - ii. Invited 3 community partners to participate in NCRP Seminars
- b. Development of a UM ‘certification’ process for Clinical Research Professionals in collaboration with the Education and Regulatory Components.
 - i. Developing regulatory-specific education/training curriculum for the Clinical Research Professionals (U-Way workshop - complete, CBLs – nearing completion, mentoring program – in progress)
- c. Development of a UM ‘certification’ process for Clinical Research sites in collaboration with the Office of Research & Innovative Medicine, and the Education and Regulatory Components.
 - i. Began communication between clinical research units via creation of SOP committee (PIs, research unit directors) and subcommittee (study coordinators)

3. Year 3 Plans

- a. Enhance community-based partnerships to offer ¡Alianza! services, education and training
 - i. Invite community partners to participate in clinical research educational activities including NCRP Seminars to community partners
- b. Finalize development and pilot UM ‘certification’ process for Clinical Research Professionals in collaboration with the Education and Regulatory Components
 - i. 1-2 pilot groups to complete/participate in education/training curriculum
 - ii. Collaborate with the Clinical Research Operations and Regulatory Support (CRORS) office to draft implementation and follow-up/maintenance plan
- c. Finalize development of UM ‘certification’ process for Clinical Research sites in collaboration with the Office of Research & Innovative Medicine, and the Education and Regulatory Components.
 - i. ‘Certify’ 1-2 clinical research units (use of approved SOP templates, staff participation in U-Way workshop and successful completion of computer-based learning modules)
 - ii. Collaborate with CRORS office to draft implementation and follow-up/maintenance plan
 - iii. Identify changes in benchmarks with implementation of research infrastructure (i.e. time of regulatory package received to IRB approval, contract execution, patent enrollment, enrollment goal reached)
 - iv. Use these benchmarks to identify outliers and use these data to make targeted intervention
 - v. Reassess benchmarks (every 3-6 months) and intervene as necessary (ongoing)

D. MAJOR ACCOMPLISHMENTS

- Development of “Universal” operating procedures across ¡Alianza! sites.
- Active and engaged Network for Clinical Research Professionals (NCRP) has been established
- Piloted two daylong U-Way Workshops (Sept 2013, Feb 2014; 12 participants & 12 presenters); 100% participants & Presenters evaluated workshop as ‘excellent’ or ‘very good’; detailed comments will guide future workshop implementation

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, this program participated in Regulatory Key Function Committee (KFC) to create standardized clinical research coordinator education and training curriculum; ongoing exchange of information with University of Florida and University of California San Francisco CTSA; and participated in Clinical Services Core, Regulatory, and Education KFC teleconferences.

Miami CTSI Research Education, Training, and Career Development Program

Data and metrics for this program can be found in Appendices #9 (K12 scholarly activities) and #10

A. PERSONNEL **Leadership:** Neil Schneiderman, PhD, Director; Gwendolyn Scott, MD, Director
Other Personnel: JoNell Potter, ARNP, PhD, Director of Short Courses; M. Guerda Nicolas, PhD, Chair of Mentoring; Marc Lippman, MD, Chair of Mentoring; F. Daniel Armstrong, PhD, Senior Advisory, Curriculum; Carlos Sandoval, Program Coordinator

B. GOALS

The overall goals of this program are to provide an institutional umbrella for educational resources, coursework, mentoring and degree opportunities that focus on translational science for individuals and the community; and to provide mentored programs to early career investigators, students and professionals in clinical translational science.

C. PROGRESS AND PLANS

AIM 1: Provide an institutional home for research education, training, mentoring and career development in Clinical/Translational (C/T) science.

1. Year 2 Plan

- a. Continue strengthening infrastructure for research training and education through building of collaborative relationships with Miami CTSI Components and Institutional stakeholders.
 - i. Continue training personnel to provide research education navigation assistance to internal and external clients.
 - ii. Continue to promote education on culturalized health sciences, and a focus on underrepresented minorities.

2. Year 2 Progress

- a. Establish information resource and referral mechanisms regarding C/T educational and training opportunities within the CTSI/UM.
 - i. Resources fully operational.
 - ii. Web content has been continuously updated for the Master's Program to promote new registrations
- b. Resource listing pertinent training courses, funding for trainees, and mentors for the CTSI website developed.
 - i. Developed website content for each existing education program (Master's program, Boot Camp, Seminar Series), currently available.

3. Year 3 Plans

- a. Establish information resource and referral mechanisms regarding C/T educational and training opportunities within the CTSI/UM.
 - i. Continue to promote educational resources and C/T training opportunities
- b. Develop list of pertinent training courses, funding for trainees, and mentors for the CTSI website
 - i. Create and Promote webinar / informational content such as T32, Grant Writing, Master Program, PhD, K12 opportunities

AIM 2: Develop and implement short courses in C/T science.

1. Year 2 Plan

- a. Carry out "Foundations of Translational Science Bootcamp" targeting approximately 100 clinicians, research fellows and junior investigators.
- b. Launch Clinical Coordinators training and certification program.
- c. Assemble listing of Seminar/Course presentations on Clinical Translational Science.

2. Year 2 Progress

- a. Translational Science Boot Camp developed and implemented. (see Appendix #10 for full report on Translational Bootcamp)
 - i. The CTSI Boot Camp was conducted (~ 100 participants).

- Post-event proficiency test scores improved by 15%
 - ii. Developed and administered Boot camp evaluation surveys (~65% response rate); data presented to CTSI leadership.
 - 50% of attendees declared better understanding of C/T research post event
 - 40% of attendees would recommend course to a colleague
 - Survey results showed 52% of attendees were not there voluntarily which is prompting restructuring of event for year 3.
 - b. Some Clinical Research Professionals Training programs developed (involves collaboration of iAlianza!, Regulatory and the Research Ethics programs). (See iAlianza! Program narrative for details)
 - i. Began internal review of drafted CBLs (computer-based learning modules)
3. Year 3 Plans
- a. Translational Science Boot Camp.
 - i. Develop and implement a new Boot Camp structure based on findings from survey.
 - ii. Implement registration/ tracking system.
 - iii. Video learning platform incorporation
 - b. Clinical Research Professional Staff Training program developed (involves collaboration of Alianza, Regulatory and the Research Ethics programs).
 - i. Continue to collaborate with Alianza, Regulatory, and Research Ethics Programs to develop Clinical Research Professional Staff Training Program

AIM 3: Develop and implement Career Development Programs in C/T Science.

1. Year 2 Plan
- a. Monitor K12 program and provide extensive mentoring.
 - b. Enroll second class in Masters of Clinical and Translational Science and select mentors.
 - c. Become more involved with the Education and Career Development Key Function Committee.
 - d. Develop one or more mentoring courses.
2. Year 2 Progress
- a. K12 program established.
 - i. Four K12 awards have been given in two cycles, first cycle awardees (2) making significant scientific progress (Appendix #9)
 - ii. Third cycle of K12 awards launched- 25 applicants submitted letters of intent.
 - b. Progress of K12 awardees in publications and extramural support in the area of K12 tracked.
 - i. 6 month progress report and presentations held. (Appendix #9)
 - c. Early Career Clinical Faculty Investigators C/T training/mentoring program developed. (Appendix #10)
 - i. Potential candidates for the early career clinical faculty investigators training/mentoring program have been selected.
 - ii. Mentor-mentee match service created, 10 junior investigators receiving ongoing mentoring.
 - iii. Proposed mentee-mentor matches (4)
 - d. Early Career Basic Science Faculty Investigators CT training/mentoring program developed. (Appendix #10)
 - i. Developed and implemented grant writing workshop in June 2013 (~20 attendees, 100% positive feedback). (Appendix #10)
 - ii. Held second Grant Writing Workshop 1/15/2014 - 2/19/2014 (~13 attendees, 100% positive feedback). (Appendix #10)
 - iii. Developed and implemented program evaluation survey (Appendix #10).
3. Year 3 Plans
- a. Continue to fund and support K12 awardees
 - b. Track progress of K12 awardees in publications and extramural support in the area of K12.
 - c. Develop and Implement training for submission of T32 programs.
 - i. Develop video Webinar
 - d. Early Career Clinical Faculty Investigators CT training/mentoring program.

- i. Organize regular mentor-mentee meetings
- ii. Develop research network collaboration
- e. Early Career Basic Science Faculty Investigators CT training/mentoring program.
 - i. 3 Grant writing seminars June-July / November-December / February-March
 - ii. Create and promote video training

AIM 4: Develop degree programs and concentrations in C/T Science.

1. Year 2 Plan

- a. Launch the PhD concentration in Clinical and Translational Science, including development of C/T coursework for current Ph.D. concentrations and definition of mentorship role for new concentration.
- b. Develop content for and organize a workshop focusing on the development of T32 programs in Clinical and Translational Science.

2. Year 2 Progress

- a. Master's degree program in C/T science.
 - i. Master's Degree Program in Clinical and Translational Science has been initiated.
 - 7 students have completed 2 semesters of Master's program. (Appendix #10)
 - ii. Recruited a new Master's degree class (Aug 2013), 5 new students enrolled in the Master's program
- b. Establishment of a Ph.D. Concentration in C/T science.
 - i. Meetings have been held between the program co-directors and graduate training directors to begin developing Clinical and Translational Concentrations in what are now basic science PhD programs.
 - ii. Translational PhD concentration has been approved by Medical School Graduate Program Directors

3. Year 3 Plans

- a. Master's degree program in C/T science.
 - i. Video clip about the Master's program on UHealth TV (shown across medical campus)
 - ii. Showcase Master's program on Miami CTSI Website
 - iii. Recruit new class after May 1, 2014
- b. Ph.D. Concentration in C/T science.
 - i. Promote Ph.D. C/T concentration track
 - ii. Establish steering committee for PhD concentration track

D. MAJOR ACCOMPLISHMENTS

- Master's program filled to capacity
- C/T Bootcamp held with approximately 100 participants
- Mentorship programs implemented

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, program leadership participated in Education and Career Development Key Function Committee meetings and activities.

Miami CTSI Community Engagement and Cultural Diversity Program (CECD)

Data and metrics for this program can be found in Appendix #11

- A. PERSONNEL** **Leadership:** Olveen Carrasquillo, MD, Director; Erin Kobetz, Ph D, Director; M. Guerda Nicolas, PhD Co-Director
Other Personnel: Victoria Mitrani, PhD, Investigator; John Ryan, DrPH, Investigator; and Brendaly Rodriguez, Program Coordinator

B. GOALS

The Community Engagement and Cultural Diversity program will foster long-term bidirectional mutually beneficial relationships between CTSI and our community; and provide important infrastructure and resources for UM investigators and trainees in the conduct of community-based research.

C. PROGRESS AND PLANS

AIM 1: Foster long-term participatory academic-community collaborations and assist UM investigators/students and community partners in conducting community-based and culturally competent research.

1. Year 2 Plan

- a. We will begin to focus on process areas that will result in increased input, consultation and participatory engagement of community, including our planned seminars series, Community Research Associate (CRA) who serves as a two way interface between community groups and investigators, and planned dissemination platform.

2. Year 2 Progress

- a. Mechanisms to enhance culturalized health sciences via partnerships with patients and community members and their research activities developed and implemented.
 - i. CTSI-CECD faculty and staff had **77** discrete events involving interactions and/or provision of support services to outside organizations (local, state, and national). These activities included assistance for proposals, community outreach, funding, reviewing applications, editing translations, and developing curriculum content (See Appendix #11)
 - ii. Provision of support to major grants (> \$150K) under the leadership of some our key community partners including the Health Choice Network (consortium of FQHC's, one grant funded by AHRQ, another by Bristol Myers Squibb), Health Council of South Florida (state designated group to spearhead region wide state planning, grant under review by HHS OAS) and the Miami-Dade Area Health Education Center (grant funded by OMH).
 - iii. Response to 18 media requests (local and national, English and Spanish) on several topics relating to minority health and other health topics of interest to our community such as the Affordable Care Act, health disparities, disease-specific, Latino health, and women's health. (See Appendix #11)
- b. Assistance to researchers in their collaborations with patients and community members through a researcher-focused participatory process.
 - i. CTSI-CECD faculty and staff had **107** discrete events involving interactions and/or provision of support services to UM faculty (proposal development and writing, methodology and data consultations, data collection instrument development, obtaining LOS, lectures, recruitment strategies, engagement of community partners). (See Appendix #11)
 - ii. Mentoring to 13 investigators requesting assistance in preparation of CTSI pilot and K12 funding proposals
- c. Development of inventory of best practices and tools for research with ethnically/culturally diverse populations.
 - i. Initial list of investigators/faculty identified; Script currently being developed for video vignettes on successfully culturalized research.
 - ii. Worked with Biomedical Informatics Program on race/ethnic identifiers for EMR
- d. Increased awareness of principles of community engagement and culturalized health sciences throughout the CTSI.

- i. Provided talent for speaking engagements, ground rounds and panel discussions internally at UM and with local partner organizations
- e. Develop plan to increase number of researchers with active partnership with Jackson Memorial Hospital (JMH).
 - i. Supported the coordination of the UM/JMH collaborative agreement in regards to clinical research conducted at JMH

3. Year 3 Plans

- a. Mechanisms to enhance culturalized health sciences via University faculty partnerships with patients and community members and their research activities.
 - i. Continue to provide consultative services and support to community partners and university faculty/students (on-going)
- b. Assistance to researchers in their collaborations with patients and community members through a researcher-focused participatory process.
 - i. Continue to coordinate research partnerships with community partners (on-going)
- c. Inventory of best practices and tools for research with ethnically/culturally diverse populations.
 - i. Produce, make available and track traffic for 5 video vignettes on successfully culturalized research on CTSI website
 - ii. Showcase successful participant recruitment and retention practices, community partnerships and lessons learned
 - iii. Work with informatics on uptake/collection of race/ethnic identifiers in EMR
- d. Increased awareness of principles of community engagement and culturalized health sciences throughout the CTSI.
 - i. Conduct lectures, participate in panels, and ground rounds (on going)
- e. Increased number of researchers that have a partnership between themselves with JMH.
 - i. Continue to help coordinate the processes for UM/JMH research partnerships (on-going)

AIM 2: Develop an online inventory of faculty “experts” who: work with ethnically/culturally diverse populations; interact and have relationships with community organizations; or who conduct or participate in international research.

1. Year 2 Plan

- a. We will collect information about different researchers at UM who are conducting community based research and/or research with culturally diverse communities.
- b. We will be using REDCap as a database to collate this information which will then be placed on our CTSI website so that it can easily be searchable.

2. Year 2 Progress

- a. Online faculty inventory for use by the UM community and community developed.
 - i. Through electronic searches, identified over 600 UM faculty that may potentially be in directory
 - ii. Through iterative process, developed faculty inventory of 188 entries to date, including name, contact information, educational background, content area of interest, countries and communities with which they have worked

3. Year 3 Plans

- a. Publish online faculty inventory for use by the UM community and community.
 - i. Securing faculty participation and updating faculty profiles as needed (ongoing)
 - ii. Work with SciVal and the CTSI representative from the Biomedical Informatics Program to expand the Profile Enhancer feature of the searchable inventory on the UM CTSI website

AIM 3: Develop and implement training in Community Based Participatory Research (CBPR) and health disparities research.

1. Year 2 Plan

- a. Develop and implement training programs in CBPR and health disparities research.

2. Year 2 Progress

- a. Develop training programs/modules in CBPR/Cultural Competence for UM faculty/students.
 - i. Initial development of disparities and CBPR training curriculum and lectures
 - ii. Provided lectures and training session on CBPR/Health Disparities/Cultural Competence to various UM, community and external stakeholder groups (See Appendix #11)
- b. Develop, in collaboration with iAlianza!, online community-based participatory research (CBPR) and cultural competence modules for CITI.
 - i. Reviewed current module on cultural competence on CITI
 - ii. Met with CITI staff to review draft modules being developed.

3. Year 3 Plans

- a. Develop and implement training programs/modules in CBPR/Cultural Competence for UM faculty/students.
 - i. Continue to provide training programs in programs/modules in CBPR/Cultural Competence for UM faculty/students (on-going)
 - ii. Continue to provide lectures/training in CBPR/Health Disparities/Cultural Competence to the community and other organizations (on-going)
- b. Develop, in collaboration with iAlianza!, online community-based participatory research (CBPR) and cultural competence modules for CITI.
 - i. Work with CITI UM and iAlianza! to review CITI Harvard modules for community competence, in addition to current available CITI module on cultural competence

D. MAJOR ACCOMPLISHMENTS

- Development of race/ethnic identifiers for EMR
- Identification of 188 faculty conducting community-based research at UM including name, contact information, educational background, content area of interest, countries and types of communities

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, we participated in the monthly Key Function Committee conference calls.

Miami CTSI Tracking and Evaluation Program

Data and metrics for this program can be found in Appendix #13

A. PERSONNEL **Leadership:** Sara J. Czaja, PhD, Director; Margaret M. Byrne, PhD, Co-Director
Other Personnel: Rosalina Das, Senior Decision Support Analyst

B. GOALS

The primary objectives of the Tracking and Evaluation Program are to identify ways in which the structure, processes and functioning of the CTSI can be improved to: ensure that its mission and goals are achieved, resources are distributed effectively and equitably, and the CTSI program services are appropriately configured, accessible, and utilized efficiently.

C. PROGRESS AND PLANS

AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its programs.

1. Year 2 Plan

- a. Organizational: Hire an additional technical support team member
- b. Continued Activities:
 - i. Attending the Monthly Operational Committee Meetings and the meetings of the internal and external advisory boards
 - ii. Involvement with the National Key Evaluation Function Committee
 - iii. Meet with each of the Program leaders on a regular basis (including utilizing new support team member) to discuss the progress of the program and identify any change in aims or planned activities and to refine metrics as needed.
 - iv. Meet regularly with CTSI leadership to ensure that communication on all activities related to tracking and data collection are shared among evaluation and administrative programs
- c. Metrics:
 - i. Develop metrics for longitudinal collection of data from each program and CTSI overall
- d. Tracking:
 - i. Finalize identification of databases for identified metrics in collaboration with the Biomedical Informatics Program, the Office of Research, the Office of Human Subjects, and other relevant entities
 - ii. Integrate data collection processes and summary evaluation outcome data on the Virtual Research Commons, in collaboration with members of the Biomedical Informatics Program and the CTSI leadership
- e. Outreach and development of program strategy and evaluation plan:
 - i. Finalize evaluation strategies
 - ii. Identify an External Consultant to gather further input on our evaluation strategies (the initial consultant identified in our application has since left to pursue other career opportunities.

2. Year 2 Progress

- a. Senior Decision Support Analyst hired.
- b. Set of outcome and process metrics for the overall CTSI developed.
- c. Set of outcome and process metrics for each Program of the CTSI has been developed.
 - i. Interviewed all program leaders to do a critical review of their program aims and associated metrics.
- d. Databases for tracking metrics for some Programs have been identified.
- e. System for tracking the activities of the CTSI and the programs have been developed.
 - i. The Tracking and Evaluation team has begun collaborating with the Biomedical Informatics Program to develop data tracking procedures.

3. Year 3 Plans

- a. Implement set of outcome and process metrics for the overall CTSI
 - i. Analyze strengths and weaknesses of the CTSI based on the June 2013 IOM report on the CTSA Program at NCATS (06/2014), the External Advisory Committee report and continued feedback from program leaders and university community

- ii. Update process metrics as needed according to planned activities of the overall CTSI
- iii. Identify key metrics for overall CTSI that focus on overall impact.
- iv. Complete identification of “meta metrics” for measurement of impact.
- b. Implement set of outcome and process metrics for each Program of the CTSI.
 - i. Meet quarterly with Program leaders to track progress and identify barriers
 - ii. Modify process metrics as needed to reflect changes in program activities
 - iii. Identify a set of key impact metrics for each program.
 - iv. Continue to help program leaders develop evaluation tools for their programs, such as satisfaction surveys, and others to specifically track impact.
- c. Continue to identify and integrate existing databases for tracking metrics for the Overall CTSI and each Program.
- d. Develop system for tracking the activities of the CTSI and the programs.
 - i. Deploy tracking tools for CTSI and the programs in collaboration with Biomedical Informatics Program.
 - ii. Work with Biomedical Informatics program to gather data through CTSI website.

AIM 2: Conduct a rigorous and on-going evaluation of the overall CTSI to: identify structures, services and programs that are effective and those that are in need of improvement; evaluate the CTSI impact on the clinical and research practices and productivity at UM and our collaborative partners; and evaluate its impact on UM’s community engagement activities.

1. Year 2 Plan

- a. Develop and conduct evaluation surveys with users of the CTSI program services
- b. Collect data on the identified metrics for the overall CTSI and the programs using developed tracking methodologies
- c. Summarize collected data and rigorously evaluate progress of each program and overall CTSI relative to specific aims and to plans outlined in 2014 Annual Report (current report)

2. Year 2 Progress

- a. Survey on timeliness, satisfaction and efficiency of services of CTSI services was conducted (n=240). Satisfaction ratings (1= very dissatisfied to 5= very satisfied) (See Appendix #13 for full survey results)

Core/Service	Please rate your overall satisfaction with the service you received.	Was the turnaround time satisfactory?	Were all your questions answered/addressed satisfactorily?
Combined Average Rating	4.2	4.3	4.1
Biostatistics Collaboration and Consulting Core	3.5	3.9	3.4
Clinical Research Center (CRC)	4.5	4.6	4.5
Community Engagement Consultation	4.3	4.3	4.3
Research Navigator	5	5	5
Pilot applications	4.5	4.3	4.2
K12 applications	4.5	4.5	4.4

- b. Summative (annual) evaluation of the Overall CTSI conducted.
 - i. Monthly meetings with CTSI leadership to review progress as per outcomes and metrics table.
- c. Summative (annual) evaluation of the programs conducted.
 - i. Meetings conducted with program leaders and the overall CTSI leadership to review progress.
- d. Processes of the programs evaluated.

- i. Mega Table that classifies larger categories of metrics and captures common metrics across programs is being developed.

3. Year 3 Plans

- a. Conduct summative (annual) evaluation of the Overall CTSI.
 - i. Provide feedback to CTSI leadership on CTSI progress and challenges on a quarterly basis.
- b. Conduct summative (annual) evaluation of the programs.
 - i. Provide feedback to CTSI leadership on Programs' progress and challenges on a quarterly basis
- c. Evaluate processes (e.g. timeliness and satisfaction and efficiency of services) of the overall CTSI.
- d. Evaluate processes of the programs.
 - i. Collect baseline data
- e. Evaluate impact of the CTSI on community activities.
 - i. Define metrics for assessing CTSI impact on community activities and define scope of community.
 - ii. Collect baseline data.
 - iii. Track CTSI impact on community engagement and participation in collaboration with the Community Engagement Program.

AIM 3: Conduct evaluation research to develop and test new methods/tools for evaluation.

1. Year 2 Plan

- a. Initiate one of our planned research projects related to recruitment and retention in C/T research trials

2. Year 2 Progress

- a. Reviewed evaluation literature to help guide formulation of research projects

3. Year 3 Plans

- a. Develop new evaluation methodologies/guidelines/tools.
 - i. Collect baseline data on collaborations and publications emanating from research activities.
 - ii. Map CTSI driven collaborations and publications using Social Network Analysis tools.

D. MAJOR ACCOMPLISHMENTS

- Set of outcome and process metrics for the overall CTSI and each Program of the CTSI has been developed.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Before reorganization of CTSA Consortium, the Program was actively involved in the National Key Evaluation Function Committee and other institutional CTSI Evaluation programs.