Miami CTSI Self Evaluation Report

To date, our self evaluation program activities have focused on developing metrics and building a system to track the evaluation data for the Miami CTSI and its Components.

1. Confirming the stated goals and verifying the appropriateness and feasibility of metrics originally specified for CTSI and Components
2. Identifying suitable process measures that can point to proper service provision/program operationalization or indicate system corrections, should they be needed
3. Finalizing outcome measures for each stated goal (Specific Aim)
4. Identifying the databases and working with the Office of Research and Biomedical Informatics Component to build the framework for tracking procedures and data
5. Developing the tracking system and initiating evaluation activities

In the following, we provide selected highlights of our work and how we will conduct evaluation going forward.

1. Biomedical Informatics

This Component is building the IT communication infrastructure for the CTSI and its partners. To date, we: 1) expanded the existing web environment to accommodate the CTSI web portal (Virtual Research Commons), and 2) designed the SharePoint foundation that will eventually facilitate aggregation of the CTSI's multiple knowledge/tool/information repositories across the University. Metrics for this goal include:

- # of individuals using the Virtual Research Commons (process)
- User satisfaction with the Virtual Research Commons (process)
- Deployment of the Virtual Research Commons (outcome)
- Expansion of the functionality of the Virtual Research Commons (outcome)

The Biomedical Informatics team is also garnering the resources, expertise and tools needed for data capture, management, integration, analysis and data sharing. In Grant Year 1, we 1) implemented REDCap Enterprise Research Database Tool system-wide, and 2) developed the first version of the data environment that will facilitate exploration of de-identified EPIC Electronic Health Record (EHR) data for feasibility and retrospective studies. This work included configuring the Clarity Clinical Data Repository, designing URIDE for searching "safe harbor" data, and upgrading the Velos Clinical Trials Management System. Metrics include:

- Use of and satisfaction with bioinformatics systems or consultation services (process)
- Development of new tools and integrative data services (outcome)
- Expansion and fortification of secure data platform (outcome)
- Provision of support, consultation in bioinformatics and data mining (outcome)

2. Research Ethics

The Research Ethics team works to advance and integrate ethics into all levels of clinical and translational research. Consults continue successfully, ethics reviews of Pilot Studies applications also continue and efforts to integrate ethics curriculum into existing and emerging education and training programs resulted in launching a graduate course in research ethics, a requirement in the Master of Science in Clinical Translational Investigation program. We also developed a CITI-based training module in cultural diversity and are in the process of collaborating with other Components on additional training modules for clinical research coordinators. Assuming responsibility for developing and operating the Trusted Broker Governance in collaboration with the Regulatory, BioResource, and Biomedical Informatics Components, the team started developing its structures, policies, and rules. Building in this new area of consideration, the team convened the CTSI Consortia Trusted Broker Governance Expert Workshop in Miami. Metrics include:

- Use (# of) and satisfaction with ethical consultation services (process)
- # and profile of individuals attending and satisfaction with ethics training courses (process)
- # of funded projects that have an ethics research component (process)
- # of publications related to research ethics (process)
- Successful ongoing ethics training courses and consultation services (outcome)
- Trusted Broker Governance operationalized (outcome)

3. Novel Clinical and Translational Methods, Technologies and Resources

In this Component, we advance novel technologies and translational science, linking studies with commercial potential to technology transfer resources. We manage and disseminate information about research resources, identifying need for new cores as demands emerge. To date, we have developed/reviewed business plans for all of

our cores and made sure that each had a system for tracking utilization and cost efficiency. We created the institution's core and shared resources policy that includes assuring access to external users. We completely reorganized the University's innovation team, technology advancement infrastructure, and procedures for IP assessment and formed our Drug Discovery group that now meets regularly. We successfully implemented CaneSearch day and awarded two Novel Methods Development projects and four Coulter Innovation projects. Last, we hired a Senior Fellow from "big pharma" to jumpstart networking efforts and provide commercial perspective and participated in extensive interactions with Life Science Technology Park to identify potential corporate partners. Going forward, metrics include:

- Participation in and attendee satisfaction with CaneSearch Day (process)
- # of junior faculty who begin collaborative projects (process)
- Types of core resources and # and profile of users and satisfaction with core resources (process)
- # of patents applied for and obtained (process)
- # of research studies that include Corporate partnerships (outcome)
- # of new Corporate partnerships formed (process)
- Ongoing successful operationalization of SOPs for use of core resources throughout UM (outcome)
- Successful CaneSearch Day (outcome)
- Increase in the # of CT collaborative projects (outcome)
- Increase in successful linkages of faculty with corporate/business partners (outcome)

4. BioResource

The BioResource team is building the infrastructure for our centralized system that will facilitate harmonization, utilization, and quality improvement of the University's various biorepositories. To date, we have initiated a Users Advisory Group and a Biospecimens Adjudication Committee and established a Cost Recovery Center. Our RTS DNA storage robot system is now fully operational. We developed and implemented SOPs for tissue procurement and initiated integration of sample acquisition and tracking between the Genomics Institute and the Cancer Center Tissue Bank Core Facility. Last, in collaboration with Research Ethics, Regulatory, and Biomedical Informatics Components, we continue the process of developing an interface between EPIC EHR and clinical laboratory and pathology information systems under appropriate protections and consent. Metrics for our work include:

- Perceived impact of and satisfaction with Advisory Groups (process)
- # of investigators contributing samples to or using samples from the Biorepository and their satisfaction (process)
- # of analytical procedures processed (process)
- Use of and satisfaction with informatics storage systems (process)
- Use of and satisfaction with SOPs by research community (process)
- # of interactions across Institutes/Facilities within UM (process)
- Successfully operating Executive Committee and Advisory Groups (outcome)
- Successfully operating Cost Recovery Center (outcome)
- Standardized methods for collecting, distributing, using, and storing specimens and clinical data for samples (outcome)
- Successfully operating specimen storage systems (outcome)
- Successfully operating system that integrates data sources across UM (outcome)
- Standardization of protocols for clinical and pathological tissue annotations (outcome)
- Successfully operating standardized procedures for collection of tissue and blood derived DNA under appropriate consent (outcome)

5. Pilot and Collaborative Translational and Clinical Studies

We are working to harmonize the University's existing Pilot Programs and available reviewer pools under one umbrella. We are building a system to automate electronic application & review, facilitate marketing and outreach, and orchestrate award procedures and project evaluation. Using this system, we will build scientific depth and interdisciplinarity by working together to share reports among the federation of pilot programs to leverage, supplement, or exchange meritorious applications and promote mentorship by brokering collaborations among awardees and expert co-investigators. We have met with leaders of several University Pilot programs to begin the process of forming such a federation. We will provide supplemental grant to increase interdisciplinarity and translation to existing pilot programs and well as to make the CTSI service resources available.

We also awarded four pilot studies for which we successfully implemented a multi-layered review process, including Biostatistics and Ethics reviews, an NIH Study Section-type review panel, and a post-meeting program reviewTwo Supplemental CTSI Service Credits awards were also awarded in Year 1. Metrics for our work include:

- # of interdisciplinary collaborations fostered (process)
- Success in establishing a Federation (outcome) in which CTSI supplement awards and services are used to cement the relationship between other pilot programs and the CTSI (process)
- Use of and satisfaction with pool of reviewers by pilot programs within UM (process)
- Use of CTSI resources by pilot programs (process)
- Proportion of all qualified programs that use the automated system (outcome)
- # of pilot research projects awarded (outcome)
- # of supplements awarded through other pilot programs (outcomes)
- # of pilot research projects in the Federation awarded to minority investigators (outcome)
- Operational centralized pool of experienced reviews for pilot programs across federation (outcome)
- Indices of project yield - e.g., further federal funding for applications submitted and awarded (outcome)
- Successfully implemented mentoring program that fosters pilot awardees across the Federation (outcome)
- Successfully implemented automated system for across the Federation (outcome)

6. Study Design and Biostatistics

The Study Design and Biostatistics Component offers expert consultation and research support through the Biostatistics Collaboration and Consulting Core. The team offers educational programs to train the next generation of clinical researchers and biostatistical scientists to improve quality and quantity of our research. It develops new biostatistical methods to move translational research forward. To date, we have successfully initiated our consulting core and implemented Biostatistics Clinics and Roundtables. We funded three methods development pilot projects and had nine methods biostatistics grants awarded (NSF and NIH). We successfully launched MS and PhD programs in Biostatistics, the latter with 7 students already. We integrated the NIH-funded P30 Center for Prevention Implementation Methodology and NIH-funded Prevention Science Methodology Group Component activities and increased NIH and NSF funded grants in methodology at the University. Metrics include:

- Establish Center for Statistical Sciences (outcome)
- # of and profile of users and their satisfaction with use of the Center for Statistical Sciences (process)
- Type of resources/programs offered by the Center for Statistical Sciences (process)
- # and profile of users and satisfaction of user attending Biostatistics clinics (process)
- Types of services used in and satisfaction with the consulting core (process)
- Profile of users of consulting core (process)
- # of grants submitted and funded where C/T biostatistics methods is the focus (process)
- # of presentations at scientific meetings where C/T biostatistics methods is the focus (process)
- # of peer review manuscripts on novel C/T methodologies/approaches (process)
- Successfully implemented Consulting Services and Biostatistics Clinics (outcome)
- Successfully implemented training programs (outcome)
- Success in developing new methods for analysis, assessment in C/T research (outcome)

7. Regulatory Knowledge and Support

The Regulatory Knowledge and Support Component provides consultation, guidance, and investigator-focused regulatory tools, consultation, and training activities. It offers expertise and support in clinical research quality improvement activities. The team helps investigators learn how to prepare and maintain regulatory documents and interact with regulatory agencies. To advance study participant safety, research participant advocacy services and a data & safety monitoring resource are being developed. To date, we successfully established our consult service and developed the DSMP and research participant advocacy frameworks. We authored a CITI-based training module in cultural diversity and are in the process of developing additional training modules for clinical research coordinators and compliance topics. The Office of Regulatory Support and Quality Assurance provided seminars on regulatory issues. IRB Share is up and running at the University. Last, in collaboration with the Office of Regulatory Support and Quality Assurance, ¡Alianza!, and the Research Ethics and Research Training Components, we initiated a multi-CTSA effort to build a research coordinator career ladder, standardize job descriptions, and offer a concomitant training curriculum. This is a very high priority at our University voiced both by our Vice Provost for Research and School of Medicine Executive Dean for Research and has been very well received by members in the CTSA Consortium. Metrics include:

- # and profile of users of and satisfaction with consult and study participant advocacy services (process)

- # and profile of training attendees (process)
- # of training courses/seminars offered and user satisfaction with them (process)
- Successful operationalization of study participant advocacy services (outcome)
- Successfully implemented services and training related to regulatory activities (outcome)
- Successful educational programs to improve knowledge of regulatory requirements (outcome)
- Implementation of a Universal Consent form for participation in C/T research

8. ¡Alianza!, Miami Center for Research Participation and Partnership (MCRP2)

In ¡Alianza! we are working to establish a network of centralized, affiliated locations for patient-oriented research. We are enhancing infrastructure to ensure highest ethical and regulatory standards and promote scholarly activity while accelerating the pace of research translation. We are also building a centralized core that will offer activities to enhance education, training, competency, career development, and productivity for research professionals. We started a Network of Clinical Research Professionals (NCRP) and are planning monthly gatherings to provide networking and a venue for communication and enhancing clinical research standardization across sites. We have established the Young investigator Award and, working with the Research Training, Research Ethics, and Regulatory Components, are well into the process of developing a clinical research support staff education program and web-based regulatory training modules. In line with this activity, we are developing preceptor program and certification process for clinical research professionals. In collaboration with the Office of Regulatory Support and Quality Assurance and the Research Ethics, Regulatory, and Research Education Components, we initiated a multi-CTSA effort to build a clinical research coordinator career ladder, standardize job descriptions, and offer a concomitant training curriculum. Selected metrics for our Component include:

- #, profile, and satisfaction of investigators using Clinical Research Support (process)
- Characteristics and satisfaction of users of Sharepoint-based resources/processes (process)
- Participation in NCRP meetings (process)
- #, profile, and satisfaction of attendees at seminars and training programs (process)
- # and satisfaction of community-based partners who use MCRP2 resources (process)
- Use of preceptors (process)
- Successfully implemented a standardized set of procedures and certification for CRC facilities (outcome)
- Successfully implemented uniform research laboratory and fee structure (outcome)
- Successfully implemented networking and training/educational programs (outcome)
- Successfully operationalized Sharepoint NCRP platform for social networking (outcome)
- Successfully operationalized Career Ladder (outcome)

9. Research Education, Training and Career Development

In this Component, we serve as the institutional home for research education, training, mentoring and career development in clinical/translational science. Programs include research boot camps, short courses offering certification, mentoring programs that include K12-sponsored research career development, work force development activities, graduate programs in clinical and translational research/science, and, importantly, a training-the-mentor program. Currently, our Research Boot Camp and Master's in Clinical and Translational Investigation are up and running. We have awarded two K12s and initiated a University-wide mentoring program. With Vice-Provost's endorsement, in collaboration with Alianza!, the Office of Regulatory Support and Quality Assurance, and the Regulatory and Research Ethics Components, we started to develop our training and certification program for clinical research professionals. Selected metrics for our work include:

- Types of short course offerings (process)
- Perceived satisfaction with research education/training offerings (process)
- #, profile, and satisfaction of clinical research professionals who participate in training and certification activities (process)
- # of K12 awards resulting in further federal funding (process)
- # of minority or underrepresented individuals in the degree programs and career development programs (process)
- # of minority investigators receiving K12 awards (process)
- # and satisfaction of students receiving mentoring (process)
- # of mentors involved, expertise/background of mentors (process)
- # and satisfaction of students successfully completing MS in C/T Science and C/T PhD tracks (process)
- Successfully operating system to track trainee progress and academic output of mentees (process)

- Successfully implemented research boot camps and short course offerings (outcome)
- Successfully operated MS in C/T Science and C/T PhD tracks (outcome)
- Successfully implemented K12 and mentorship programs (outcome)
- Academic outcomes of graduate students and research mentees (e.g., faculty positions, publications, grants) (outcome)
- Successfully implemented certification program for clinical research professionals (outcome)
- Increased # of T32s

10. Community Engagement and Cultural Diversity

In this Component, we foster long-term participatory research collaboration in community, assist investigators in conducting community-based research and offer training programs in Community Based Participatory Research (CBPR) and health disparities research. In addition, we strive to change the Institutional/investigator culture in which studies involving community do not engage the community up front. We have already increased and strengthened collaborations and partnerships with several CBOs and provided much needed assistance and mentoring to investigators and trainees requesting CTSI funding in this area. We have also developed disparities and CBPR training programs and curriculum content. Metrics for this goal include:

- Use of and satisfaction with mentoring services and Resource Center (process)
- # of new partnerships with CBOs (process)
- # of new grant applications that include minority health disparity components or are a result of community/community practice collaborations (outcome)
- # and profile of junior investigators awarded funding for community-engaged research (outcome)
- Development and implementation of training programs (outcome)
- # and profile of individuals in training program, satisfaction with training programs
- CBOs satisfaction with investigators who appropriately engage them prior to grant submission

11. Tracking and Evaluation

This Component is working very closely to develop the metrics and tracking systems for the overall CTSI and its Components. Additional goals are to conduct evaluation research to develop and test new methods and tools for evaluating the impact of structures like the CTSI on research philosophies, practices and outcomes. To this aim, specific metrics include:

- Development of new evaluation methodologies/guidelines/tools (outcome)
- Publications emanating from research activities (outcome)
- Submission and award of new grants/supported research projects related to evaluation (outcome)
- Obtain IRB approval (process)
- Formalize research protocol (process)
- Collect and analyze data (process)

Miami CTSI Component 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

A. PERSONNEL

Leadership

- José Szapocznik, PhD, Director, Miami CTSI
  Chair, Department of Epidemiology and Public Health, University of Miami School of Medicine
- Jonelle Wright, PhD, Co-Investigator and Associate Director, Miami CTSI
- Elaine Van der Put, PhD, MSPH, Chief of Strategic Operations, Miami CTSI
  Chief Strategy Office, University of Miami School of Medicine

Other Personnel

- Sheela Dominguez, CRA, Director of Strategic Operations
- Stellamarina Covelli, Fiscal Manager
- Patricia Avissar, Research Navigator
- Raquel Perez, Communications Manager/Website Content Editor
- Yvonne Mejias, Fiscal Assistant
- Lynn Suarezapecheche, MBA, Executive Assistant

B. GOAL

Provide administrative, fiscal and programmatic support to all CTSI components. Coordinate inter-component activities and align components 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 Components in order for them to achieve their major milestones.

C. CHARACTERISTICS

1. Overview of Functions:
   a. Governance: The Chief Strategy Officer for the Medical Center is a member of the CTSI leadership team. This helps align University, Medical Center and CTSI strategic goals. The CTSI leadership group participates in the Office of Research and Innovative Medicine Research Cabinet, which meets weekly
   b. Planning: The strategic planning process for the CTSI is aligned with overall strategic planning for the Health system
   c. 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.
   d. CTSI website design, content development, and management
   e. Customer relations: Documentation and dissemination of information regarding CTSI programs, services, cores and personnel
   f. Research Navigation: Support for all Institutional researchers in regards to existence and access to core facilities, funding opportunities, research services, etc.
   g. Coordination of internal and external reporting, including Progress reports
   h. Fiscal: budget management and reporting, purchasing, expenditures approval and control, capital asset management
   i. Project management of major component and inter-component initiatives, such as Pilot Projects and Mentored Career Awards coordination and support
   j. Event Management: Organization of all major events, including External Advisory Committee, NIH Program Officer visit, CaneSearch (annual research day), major seminars and forums, etc.
   k. Human Resources: organizational chart, position description, recruiting, onboarding, training, evaluation, payroll, vacations, effort reporting
   l. Facilities: space management, telephones, furniture; purchase and allocation of computers, equipment and supplies for all CTSI components
   m. Administrative Support: scheduling, travel, reporting, agendas, presentations

2. Progress:

a. Personnel: Recruitment of all staff members listed in Section A. Creation of job descriptions, posting of positions, selection, hiring, onboarding.
b. CTSI Headquarters: Negotiation of allocation of dedicated space for CTSI headquarters, located in the 7th floor of the Clinical Research Building at the School of Medicine. Currently 740 square feet, to be expanded to 2,500 square feet of contiguous space where the Associate Director and all staff are collocated.
c. Committee/Program Meetings:
   - **CTSI Leadership Team** – Meets weekly, usually more often to address issues, problem solve, manage operations, advance work on Component-specific and overall CTSI strategic goals
   - **CTSI Administrative Core Team** – Meets weekly
   - **Executive Committee** – Meets monthly
   - **External Advisory** – Meets twice a year, once in person and once via conference call
   - **Internal Advisory** – Meets quarterly
   - **Scientific Advisory** – Meets quarterly
   - **Office of Research and Innovative Medicine-CTSI Alignment** – Meets monthly
   - **Provost Meetings** – Initially, met monthly. Decreased as CTSI start-up stabilized
   - **CTSI Community Advisory** – Meets twice a year; Next meeting scheduled for April 29, 2013
   - **Operational Leadership** (all Component Directors) – Meets monthly
   - **Component-Specific Working Groups** – Meet twice-weekly 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. Compilation of application, selection of reviewers, review process, coordination of material for review committee, feedback to awardees and applicants
   - Support for Research Education component: Support in developing, reviewing, and awarding Mentored Career Development Awards (KL2). Compilation of application, selection of reviewers, review process, coordination of material for review committee, feedback to awardees and applicants
   - Support for Novel Methods in overall coordination of CaneSearch, University-wide Research Day on February 27, 2013. The Community Advisory Board has identified Obesity as a major health concern for the diverse South Florida community, and the theme was adopted as the focus of the inaugural research day, “CaneSearch.” Keynote speakers included Dr. John Ruffin, Director of the National Center on Minority Health and Health Disparities, and Dr. David Nelson, Director of the UF CTSI. The daylong event, attended by more than 500 people, was comprised of a poster session that featured 70 scientific posters on obesity-related topics, 40 core and central resource posters, and 10 community partner posters. The event also featured a Collaborative Research Exchange Forum, at which speakers gave presentations on topics ranging from obesity science to interventions. The panel discussions brought together experts from various disciplines, including medicine, architecture, Miami-Dade County Parks and Open Spaces, psychiatry, engineering, pediatrics, surgery, and genetics.
   - Support for Novel Methods in overall coordination of Hack-a-thon, which took place on March 23-24, 2013. Concurrent to CaneSearch and in conjunction with Lift 1428, a Miami-based innovation, design, & strategy firm, the Miami CTSI hosted Impact Obesity, a unique hack-a-thon event that sought to inspire innovative business ideas that incorporate technology to manage and reduce obesity in minority communities. Over 2 days, 5 teams that included web developers, programmers, graphic artists, medical and Ph.D. students collaborated on solutions to fight obesity. Teams had access to UM researchers and healthcare experts and development support from Rokk3r Labs, an entrepreneurial start-up company. Winners were awarded CoWork Space at the Miami Innovation Center and an invitation to submit for further funding from the Miami CTSI. The first place winner was a project called “No Obese City,” a multilingual portal to engage parents and children to live a healthy lifestyle. Parents with children in school lunch programs would be able to track their child’s nutritional intake and daily physical activity.
e. Coordinated the first NIH-NCATS Program Officer visit on January 14th , 2013

f. Presentations: A total of 34 presentations were conducted to market the CTSI, explain and disseminate services provided, and also to gather input of how to best help improve UM's research infrastructure. Some highlights were:
   - Presentations from José Szapocznik, Miami CTSI PI and Jonelle Wright, Miami CTSI co-investigator to the Medical School Faculty Council, the faculty of the Schools of Marine Science and Nursing, and to the Faculty Senate
   - Elaine Van der Put, Miami CTSI's Chief of Strategic Operations, presented weekly updates on the CTSI's progress to the Core Executive Leadership Group of the School of Medicine. This group is composed of the Dean, the Chief Operations Officer of the Health System, the Executive Deans for Research, Clinical and Education, the CFO, the Heads of Human Resources and Information Technology.
   - All components presented their goal, priorities for the first year and detailed action plan to the Office of Research and Innovative Medicine Research Cabinet

g. Coordination and Logistical support for a half day NIH Grant Resubmissions workshop, part of the SEEDS program (Scientists and Engineers Expanding Diversity and Success) in collaboration with the Office of Research and Innovative Medicine

h. Developed Miami CTSI's first Annual Progress Report

3. Highlights (see Highlights, Milestones, and Challenges Report):
   - CTSI support for improvement of IRB systems:
     IRB 7.2 is a pre-configured IRB submission and workflow system designed to be compliant with federal regulations and which also meets requirements for AAHRPP accreditation. It is based on the same software platform that is used for our current IRB system, but with the incorporation of the HRPP Toolkit developed by Huron Consulting Group, which provides a pre-defined set of IRB forms, SOPs, checklists, and templates. This will lead to increased efficiencies within the Human Research Protection Program as well as provide investigators and study teams with a streamlined application process further reducing time and cost associated with the preparation of submissions for IRB review. Of note is that while this will present a much needed reprieve for PI's and study teams who are also struggling with financial challenges and competing priorities, this will represent an increased workload onto the HSRO/IRB regulatory team. However, the institution remains committed to retaining and recruiting highly qualified regulatory personnel to the HSRO. We will also continue to ensure the high quality of reviews including maintaining regulatory compliance and appropriately capturing all requisite reporting needs. It is expected that the transition to IRB 7.2 will lead to improvements and increased efficiencies in the overall Human Research Protection Program at UM.

D. PLANS FOR COMING YEAR

1. Expansion of CTSI Headquarters to 2,400 square feet, including creation of Research commons space with dedicated consultation and meeting rooms for CTSI participants and stakeholders.
2. Planning and execution of first External Advisory Committee meeting.
3. Planning and execution of first Miami CTSI Strategic Planning retreat.
4. Support for key events, such as CaneSearch, Innovation Showcase, major seminars, etc.
5. Fine tuning and dissemination of metrics, including creation of tracking systems (e.g. databases).
6. Development of a comprehensive Miami CTSI Communications Strategy
   - Creation of CTSI newsletter and other CTSI communications tools
7. Elaine Van der Put, CTSI's Chief of Strategic Operations was tasked to lead a team to completely redesign Research support operations for the Miller School of Medicine. For this matter, Elaine will be dedicating effort on the recently created role of "Office of Research and Innovative Medicine Strategy Officer", in charge of Research Solutions. This dual role will further emphasize the critical contribution of the CTSI towards the improvement of Research Infrastructure at UM.

Miami CTSI Biomedical Informatics

A. PERSONNEL: **Leadership:** David Seo. MD, Co-Director; Nick Tsinoremas,PhD Co-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 component is to provide the communication foundation for the Miami CTSI, build interconnectivity and interoperability among Miami CTSI components, 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.

1. AIM 1: Catalyze communications among the CTSI and its partners
2. AIM 2: Expand and develop resources, expertise and tools for data capture, management, integration, analysis and data sharing
3. AIM 3: Explore opportunities for education, training and mentorship in Biomedical Informatics to advance clinical/translational science

C. CHARACTERISTICS

1. Action Plan for Year 1: The YR1 action plan focused on requirements discovery with Principal Investigators, development and testing of the first alpha version of Clinical Data Environment, discussions of Biorepository goals, collaboration with Trusted Broker for the development of data access policies and procedures, and the completion of FDA CFR 21 Rule 11 validation of Velos.

2. Progress:
   a. Engage with the Ethics and Regulatory components in the delineation of policies and procedures required to govern data access, catalyzed around HIPAA, IRB and other regulatory standards.
   b. Engage in extensive discussions with the Bioresource and Evaluation components.
   c. Facilitate the discussions about education and training with regards to Biomedical Informatics.

3. Opportunities, challenges, strengths, weaknesses and changes
   a. *Opportunities*: (i) Multiple sources of clinical and basic science information are available and can be harvested to catalyze research. UM is undertaking a major effort in moving to digital information.
   b. *Challenges*: (i) Budget limitations, (ii) Scarce resources, (iii) Need for continued EMR Rollout, (iv) Evaluation of data quality and completeness under way, (v) Pending policies and procedures for electronic data access, (vi) Limited Biomedical Informatics academic faculty.
   c. *Strengths*: (i) Center for Computational Science specialized resources in concept search and data mining of complex information (ii) University of Miami IT commitment towards development of Clinical Data Environment that includes Epic EMR data
   d. *Weaknesses*: (i) resource limitations. Digitalization of information still in progress. Still requiring to build use case of how this information can influence the research and outcomes
   e. *Changes:* (i) Needs assessments will facilitate the evaluation of requests and the process of prioritizing of the development activities.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1:
   a. Secured hardware; completed the design and implementation of the UM CTSI website database; configuration of the content management system; initiated testing phase.

2. AIM 2:
   a. Developed first version of the Clinical Data Environment using the EPIC Electronic Health Record that will facilitate exploration of de-identified data for feasibility and retrospective studies.
   b. Completed Initial design for URIDE for searching “safe harbor”

c. Completed implementation of REDCap Enterprise Research Database Tool, and established IT support at no charge for investigators interested in using it.
    i. RedCap currently has 63 registered users and 33 projects, of which 24 are in development and 8 already in production.
d. Completed Velos Clinical Trials Management System application, database and server upgrades.
e. Velos Clinical Trials Management System underwent successful computer system validation and was made compliant with FDA CFR 21 Rule 11 regulations
f. Completed initial round of needs assessments for the University Research Data Environment (URIDE). We interviewed key investigators from the Sylvester Cancer Center, Neurology, Family Medicine, Pathology, Genomics, Epidemiology, and Center of Family Studies, amongst others. The final needs analysis was focused on identifying commonalities amongst the group to ensure URIDE development efforts will focus on functionality that will benefit the community of clinical and translational scientists. The commonalities will be shared with the CTSI components and serve as the initial design of the system. The strongest commonality was to be able to facilitate retrospective and feasibility studies. We plan to engage this group of investigators in further discussions to serve on an advisory panel to further delineate enhancements for future releases of URIDE.

3. AIM 3
    a. Conducted seminars and training classes to address the informatics tools and methodologies in C/T science.
    b. Initiated discussions with faculty and medical specialty departments to explore options in terms of education and training. We have identified Dr. Sawsan Khuri to serve as the lead to guide these discussions on behalf of the CTSI.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. We attended meetings with the Biomedical Informatics workgroup
2. We participated in activities with our CTSI components and other CTSI partners from other institutions.

F. PLANS FOR COMING YEAR

1. AIM 1:
    a. Develop a phased project plan for the implementation of the CTSI website and initiate Phase I, a repository for SOP's and other documentation

2. AIM 2
    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. Continue work with Ethics Component to create the informatics infrastructure required to define and implement Trusted Broker policies.
    c. Collaborate with the Trusted Broker in discussions centered around the subject of data access and sharing of PHI.
    d. Develop the 1st version of "Concepto", the URIDE concept query tool.
    e. Interview additional investigators to gather feedback of the "Concepto" query tool; refine initial use cases with additional features.Continue the engagement with the Bioresource component and develop a searchable tool for all participating biorepositories
    f. Complete FDA CFR 21 Rule 11 computer system validation of the EProst IRB management system.
    g. 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.

3. AIM 3
    a. Expansion of the current 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 Institutional Dashboard and Evaluation Support.
c. 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.
d. 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
e. Explore Data Sharing and Contributions to CTSA Consortium
f. Collaborate with Education Component 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 which may include that we need to postpone the degree path and focus only on training for the near future.

Miami CTSI Research Ethics Component Narrative Report

A. PERSONNEL

Leadership: Kenneth W. Goodman, PhD (Director, University of Miami Bioethics Program); Paul Braunschweiger, PhD (Executive Director and Co-Founder, Collaborative Institutional Training Initiative - CITI Program at the University of Miami)

Other Personnel: Robin N. Fiore, PhD (Director, Special Ethics Initiatives; Co-Director, Research Ethics Consultation Service); Reid Cushman, PhD (Director, Responsible Conduct of Research Program; Co-Director, Research Ethics Consultation Service); Ana Bezanilla, MHSA Administrator, Ethics Programs

B. GOALS

The transformation of the clinical research enterprise significantly depends on the development of a trustee function for biobanking and electronic patient record research, a researcher-friendly Research Ethics Consultation Service, and integrated research ethics education in support of these and other CTSI efforts. The Miami CTSI will feature a comprehensive Ethics Component comprising 1) research ethics integration, 2) training in the responsible conduct of research, and 3) research on research ethics. Our objectives in developing the Ethics Component of the CTSI include the following specific aims:

1. AIM 1**:** Integrate ethics into all levels of translational research and provide ethics infrastructure for CTSI Components, investigators, and trainees.
2. AIM 2**:** Integrate ethics into education and training programs for Clinical and translational researchers.
3. Aim 3: Conduct research on research ethics

C. CHARACTERISTICS

1. Acton Plan for Year 1
   a. AIM 1
      i. Research and collaboratively conceptualize integrated ethics governance for new research environment (bioreprositories and electronic health records)
   b. AIM 2
      i. Design and implement new CITI Program courses for distribution across CTSIs
      ii. Revise Research Ethics Consultation Request process and service procedures
      iii. Reformulate UM Ethics Programs' signature monthly Dialogues in Research Ethics (DRE) series to include speakers and topics emphasizing translational science
      iv. Begin recording selected Dialogues in Research Ethics (DRE) sessions for Web streaming
      v. Sponsor periodic research ethics and translational science programming within existing departmental/component/program series
   c. AIM 3:
      i. Conduct research on research ethics education and research integrity using CITI Program data base and other programs
      ii. Complete CITI hire for CTSA research position
2. Progress in Year 1
   a. AIM 2:
      i. Met regularly with BioResource, Biomedical Informatics, and Regulatory components to establish cooperation, timelines and division of labor with respect to the development of governance and accountability structures
      ii. Worked on collecting pertinent background materials including forms and policies from other CTSAs to be made available to other Miami CTSI personnel
      iii. Identified challenges and deliberated re preliminary approach to consent and governance
      iv. Initiated interactions with CTSA counterparts at other institutions leading to future collaborations
   b. AIM 2:
      i. Implemented and performed Ethics review of all Miami CTSI Year 1 awards

ii. Reviewed and revised Research Ethics Consult procedures
iii. Implemented new procedures for online requests for research ethics consults
iv. Conceptualized new CITI Program course for Clinical Research Coordinators and Administrators (CRC/CRA) with partners at Harvard and USC CTSIs.

c. AIM 3:
i. Opened Human Subjects Research protocol for evaluation research on consult process.
ii. Interviewed candidates for CITI/CTSI research position.

D. MAJOR ACCOMPLISHMENTS, IMPACT

1. AIM 1:
   a. Worked on collecting pertinent background materials including forms and policies from other CTSAs to be made available to other Miami CTSI personnel
   b. Organized Biobank Governance Workshop with six other CTSAs February 24-26, 2013. Reported Workshop findings to KFC Ethics and KFC Ethics-Biobank Workgroup March 2013. Written report in progress.
   c. Goodman and Fiore presented on Miami CTSI Biodata Trustee System (BTS) Workshop at American Medical Informatics Association (AMIA) *Joint Summits on Translational Science* meeting, March 2013.
2. AIM 2:
   a. Reviewed all pilot grants awarded by Miami CTSI December 2012 and March 2013
   b. Implemented new procedures and online request for consults
   c. Organized educational sessions on translational topics and culturalized medicine including:
      i. "Communicating Research Risks," Ana S. Iltis, PhD, Wake Forest University
      ii. "Academy of Research Excellence – Celebrating Translational Science," Ray E. Moseley, PhD, University of Florida
      iii. "Health Disparities, Immigrants and the U.S. Health Care System," Alejandro Portes, PhD, Princeton University, and Olveen Carrasquillo, MD, University of Miami
      iv. "Renovating the Brain: Reflections on Disability, Culture and Bioethics," Jon Mukand, MD, PhD, Southern New England Rehabilitation Center
3. AIM 3:
   a. Developed Human Subjects Research protocol for evaluation research on consult process.
   b. Interviewed candidates for CITI research position.
   c. Completed planning for design and implementation of new CITI Program course for Clinical Research Coordinators and Administrators (CRC/CRA) (collaboration with with Harvard CTSI and USC CTSI)

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Organized Workshop with six other CTSAs on Biodata Trustee System (BTS) governance and design issues, February 24-26, 2013: Vanderbilt, Duke, MCSC, JHU, UF, and Michigan. Reported findings to CTSA Key Function Ethics and Biobank Workgroup and presented to ELSI (Ethics Legal Social Implications) Workgroup at *Translational Science* meeting, March 2013. Manuscript in progress.
2. Joined CTSA KFC-Ethics subgroups on Research Ethics Consultation and Biobanks.

F. PLANS FOR COMING YEAR

1. Continue working with the BioResources, Biomedical Informatics, and Regulatory components to complete the design of all elements of the Biodata Trustee System (BTS) including structure, design, rules, policies and procedures.
2. Complete a manuscript based on the February 2013 Biodata Trustee System (BTS) governance Workshop.
3. Evaluate existing Collaborative Institutional Training Initiative (CITI) survey instruments and delivery systems, retrieve and analyze data from existing surveys to improve systems.
4. Update research protocols and begin deploying new surveys on focused research ethics topics relating to diversity and related Miami CTSI topics

5. Implement new CITI Program course for Clinical Research Coordinators and Administrators (CRC/CRA) (in conjunction with Harvard CTSI and USC CTSI) and our CTSI components, Alianza!, Education and Regulatory.
6. Present on Biodata Trustee Systems at the American Society for Bioethics and Humanities 2013 annual meeting in conjunction with other CTSA institutions.
7. Continue Research Ethics Consultation Service RECS support across the institution
   a. Develop and roll out a short training experience
   b. Address integration issues in support of transformative goals.
8. Collect data from CITI under newly revised protocols on select research ethics topics and share the results with other CTSIs
9. Develop joint ethics projects with the University of Florida CTSI on research ethics issues, initiatives and projects.
10. Continue CTSI/UM Ethics Program Seminar series to provide programming and education including *Dialogues in Research Ethics and* existing Grand Rounds series.

Miami CTSI Novel Clinical & Translational Methods, Technologies & Resources

A. PERSONNEL

Leadership: Norma Kenyon, Director; Jeffery Vance, Co-Director; Herman Cheung, Co-Director
Other Personnel: Tamara Levine, Sr. Business Manager; Andrew Vinard, Manager of Biotechnology Resources

B. GOALS

1. AIM 1:Facilitate access and utilization of core resources, identify need for new cores
2. AIM 2:Accelerate the development of novel clinical and translational methods by promoting interdisciplinary research
3. AIM 3: Provide a mechanism to link studies with commercial potential to technology transfer resources
4. AIM 4:Track development of CTSI-sponsored novel methods and address incorporating multidisciplinary work into tenure track system

C. CHARACTERISTICS

1. Overview:
   The purpose of this component 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.
2. Action Plan for year 1:
   a. AIM 1:
      i. To offer more comprehensive capabilities and greater access for investigators, while ensuring continuous quality control practices for each resource, we will coordinate existing and proposed resources in a consolidated platform that harmonizes research cores across UM.
   b. AIM 2:
      i. We will strive to eliminate long-standing barriers to institution-wide cross-cutting research initiatives and provide the wherewithal for scientists and clinicians to collaborate.
   c. AIM 3:
      i. We will continue working to identify meaningful discoveries (not only medical product candidates, but technologies developed in all of our scientific disciplines across our three UM campuses (e.g. engineering, medicine, physics, marine biology, etc.) and help research teams to develop them, and to advance those discoveries through all the stages required toward commercialization.
   d. AIM 4:
      i. We will track the development of novel methods and technologies that arise from implementation of our overall strategy.
      ii. Launch University-wide initiative to have promotion and tenure practices fully embrace interdisciplinary research team members' contributions.
3. Progress for Year 1:
   e. AIM 1:
      i. Reviewed all UMMSM cores – business plans, tracking of utilization and cost efficiency
      ii. Creation of core and shared resources policy, including access protocol for external users
      iii. Reorganization of technology advancement/innovation team, procedures for intellectual property (IP) assessment and management of IP pipeline
      iv. Review of applications for service credits
   f. AIM 2:
      i. Planned for CaneSearch, and Collaborative Research Exchange Forum
      ii. Developed and issued RFP for Wallace H. Coulter Center for Translational Research Awards
      iii. Reviewed and awarded requests for interdisciplinary support
   g. AIM 3:
      i. Maintained Drug Discovery group meetings and planning
      ii. Jumpstarted entrepreneur/business networks and incorporate commercial perspectives
      iii. Interacted with Life Science & Technology Park to identify new potential corporate partners
      iv. Held "Lunch and Learn" sessions at Life Science &Technology Park
      v. Continued to decrease patent costs and increase licensing agreements and revenues
      vi. Identified and engaged local business people and entrepreneurs

h. AIM 4:
   i. Reorganized technology advancement infrastructure
   ii. Met with the Deans of all UM schools and colleges to assess needs, opportunities for development of Intellectual Property
   iii. Worked with Business School to establish new course to engage graduate students in development of intellectual property; business plans, market analysis, etc.
   iv. Worked on connecting investigators

D. MAJOR ACCOMPLISHMENTS AND IMPACT

2. AIM 1:
   a. New Manager for Biotechnology Resources (A. Vinard)
   b. Reviewed all Medical School cores – business plans, tracking of utilization and cost efficiency
   c. Created core and shared resources policy, access to external users
   d. Completely reorganized technology advancement/innovation team, procedures for intellectual property (IP) assessment and management of IP pipeline
   e. Service credits for selected users
3. AIM 2:
   a. CaneSearch (February 2013), university wide research day, focused on obesity.
      The Community Advisory Board identified Obesity as a major priority in addressing the health of the diverse South Florida community, and the theme was adopted as the primary focus of the inaugural research day event, “CaneSearch.” The keynote addresses of the day were given by Dr. John Ruffin, Director of the National Center on Minority Health and Health Disparities, and Dr. David Nelson, Director of the UF CTSI. The daylong event was attended by more than 500 people, and was comprised of a poster session that featured more than 70 scientific posters on obesity-related topics, 40 core and central resource posters, and 10 community partner posters. The event also featured a Collaborative Research Exchange Forum (CREF), at which speakers presented topics ranging from Obesity science to interventions, as well as a family testimonial. The panel discussions brought together experts from various disciplines, including medicine, architecture, county parks and recreation, psychiatry, engineering, pediatrics, surgery, and genetics.
   b. Hack-a-thon (March 2013): The Miami CTSI, in conjunction with Lift 1428, a Miami-based innovation, design, & strategy firm, hosted Impact Obesity, a unique hack-a-thon event that sought to inspire innovative business ideas that incorporate technology to manage and reduce obesity in minority communities. Over 2 days, 5 teams that included web developers, programmers, graphic artists, medical, and nutrition students collaborated on solutions to fight obesity and compete for resources to help take their ideas to the next level. Teams had access to UM researchers and healthcare experts and development support from Rokk3r Labs, an entrepreneurial start-up company.
      Winners were awarded CoWork Space at the Miami Innovation Center in the Life Science and Technology Park, and an invitation to submit for further funding from the Miami CTSI. The top place winner was a team titled “No Obese City,” which was a multilingual portal to engage parents and children to live a healthy lifestyle. Parents with children in school lunch programs would be able to track their child’s nutritional intake and daily physical activity. Second place went to “EmfaSyze,” a gaming application with a mobile interface that would help track food consumption and exercise and assign a point-system to choices and activities. Users would compete with one another for the best scores. The third place project was “Rumba Fit,” an application that shows people how to dance through virtual instruction and uses a mapping function to locate near-by dance spots.
   c. RFP issued and $400,000 awarded to four projects through the Wallace H. Coulter Center for Translational Research (Appendix 1)
   d. Two projects were awarded at $25,000 each to obtain preliminary data for interdisciplinary submissions.
      i. Project 1, Hermes Florez: Diabetes – CHAMP (Collaborative for Healthier Aging, Management and Prevention):University of Miami- CTSI/CoA/DOM/DEPH and Miami VAHS-GRECC
      ii. Project 2, Lee Kaplan: RNA Discovery in Synovial Fluid for Meniscectomy Recovery
4. AIM 3:
   a. Drug Discovery group formed and meeting regularly
   b. Hired Senior Fellow from big pharma to jumpstart entrepreneur/business network and provide commercial perspective
   c. Extensive interactions with Life Science & Technology Park to identify new potential corporate partners

d. Held first "Lunch and Learn" at Life Science &Technology Park, creating high collision innovation environment
e. Decreased patent costs based on commercialization assessment and identification of partners; increased licensing agreements and revenues
f. Identified and engaged local business people and entreprenuers, under CDA, to assist with technology assessment and/or serve as CEOs for start ups

5. AIM 4:
   a. Reorganized technology advancement infrastructure
   b. Met with the Deans of all UM schools and colleges to assess needs, opportunities for development of Intellectual Property: College of Engineering, College of Arts and Sciences, School of Architecture, School of Communications, Business School, School of Law, Marine School, School of Nursing and Health Sciences, School of Music
   c. Worked with Dean Anderson (Business School) to establish new course to engage graduate students in development of intellectual property; business plans, market analysis, etc.
   d. Senior Fellow attending lab meetings of various groups – connecting investigators
6. Community Engagement

   Most of our community engagement activity is around the Life Science and Technology Park and development of jobs and opportunities for individuals living in this underserved area; extensive interaction with park developer to engage potential new clients, community representatives and business community

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Joined the Public Private Partnerships Key Function Committee; activities in relation to consortium activities will be increased in the upcoming year.

F. PLANS FOR COMING YEAR

1. AIM 1:
   a. Creating wide-spread knowledge of, and user-friendly access to, available core and shared resources
   b. CaneSearch, Collaborative Research Exchange Forum and Shared Resources Fair (Feb 2014)
2. AIM 2:
   a. Innovation and Technology Showcase (Nov 2013)
   b. Issue new Wallace H. Coulter Center for Translational Research RFP in June 2013
3. AIM 3:
   a. Expanded outreach to stimulate innovation and develop IP across the University of Miami
   b. Work with development to identify philanthropic dollars for innovation initiatives
   c. Hire new Director for technology transfer, as well as Coulter Project Director and Entrepreneur in Residence
4. AIM 4:
   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

Miami CTSI BioResource

A. PERSONNEL: **Leadership:** Richard Cote MD, Director; Carmen Gomez MD, Co-Director; Jacob McCauley PhD, Co- Director; Phil Chen MD PhD, Co-Director
Other Personnel: Robin Fiore PhD: Ethical Integration Sub-Committee Chair

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 objectives of this Component 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 CTSI consortium. This component has 4 main aims to accomplish this goal.

1. AIM 1: Establish common governance structure to provide oversight, guidance and strategic planning

2. AIM 2: Outreach to the research community - develop customer profiles and a sustainable business plan

3. AIM 3: Develop an agile enterprise biorepository informatics infrastructure

4. AIM 4: Implement common standard operating procedures (SOPs) for consent, privacy, collection, procurement, processing, storage and distribution, and ongoing QI/QM

C. CHARACTERISTICS

1. Overview:
   The University of Miami hospitals and clinics together with Jackson Memorial Hospital serve a diverse, multiethnic community. The UM BioResource is designed to collect and distribute consented and de-identified biospecimens with associated clinical data belonging to our unique patient population. The overarching goal is to facilitate basic, translational, and clinical trial research focused on the ethnic-specific variables associated with the epidemiology, pathogenesis, genetics, biologic behavior, and therapeutic response patterns of varying disease entities, with an emphasis on community education.

2. Action Plan for Year 1: The YR1 action plan focused on laying the groundwork for an enterprise-level resource to serve the needs of the UM research community.
   a. Begin formal integration of standard operating procedures across the main physical laboratories that serve as the infrastructure for the BioResource.
   b. Explore informatics solutions to enable delivery of high-value clinical lab results to a centralized research database structure.
   c. Focus on cost-recovery initiatives to provide for long-term sustainable operations.

3. Progress in Year 1:
   a. Governance and Strategic Planning **(Aim 1)**
      i. This component, under the direction of Dr. Cote, is working within the designed structure of sub-committees to accomplished tasks across multiple focus areas within not only this component, but as they relate to other components within our broader CTSI. The Operations and IT sub-committees have been the most active as it relates to developing a common university-wide infrastructure for biospecimen data and sample tracking.
   b. Outreach, Customer Profiles, and Sustainability **(Aim 2)**

i. Drs. Gomez and McCauley have as part of the Research Community Outreach Sub-Committee met with both researchers and clinicians to discuss potential investigator-initiated projects involving current and future biospecimen collections.
ii. This sub-committee is preparing an institutional-wide users survey to promote the BioResource component and to explore the future needs of the UM network of researchers.
iii. Dr. Gomez has been participating in the NIH Cancer Genome Atlas collection efforts via the UM Cancer Center Tissue Bank and will continue these efforts to promote a sustainable resource.

c. Develop enterprise biorepository informatics infrastructure **(Aim 3)**
i. There are multiple informatics systems tracking, patient laboratory results, clinical data, and biospecimen attributes. Dr. Chen has begun implementation of numerous informatics projects and initiatives involving laboratory informatics, including implementation and ongoing maintenance of two anatomic and clinical pathology LISs, electronic public health reporting, and integration of laboratory results in Epic.
ii. The department of pathology purchased mTuitive synoptic/template reporting to ensure standardized clinical and pathological tissue annotations. These efforts are in their early phases but will provide for the necessary infrastructure to enable downstream users to extract valuable data to aid in clinical and translational research initiatives.

d. Implement common standards at an enterprise-level **(Aim 4)**
i. The implementation of common practices and standards is a complex and multi-faceted issue with multi moving parts. Drs. McCauley and Gomez have made substantial progress in aligning the procedures and standards within the two cornerstone biospecimen banking facilities, the John P. Hussman Institute's Biorepository and the Sylvester Comprehensive Cancer Center's Tissue Bank Core Facility. Weekly Operations sub-committee meetings have been established to constantly monitor this progress.
ii. This working group has begun to synergize the collection, processing, distribution and storage SOPs of these facilities. This includes the implementation of a common barcoding system for newly ascertained biospecimens, uniform sample tracking within the LIMs, and purchase of designated freezers for centralized sample storage.
iii. Common cost-sharing strategies between these banks are underway to complement the pre-existing activities of these distinct entities.
iv. The BioResource team has been engaged with members of the Ethics component to assist with the development of the Trusted Broker goals as they relate to the consenting and privacy for biospecimen collection by the BioResource component.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1:
   a. Created a "Users Advisory Group" and Tissue Adjudication Committee for the Cancer Center Tissue Bank Core Facility which will serve as the pilot process for the broader "Advisory Panel" of the BioResource.
2. AIM 2:
   a. Established 2 successful contracts for specimen collections with the NIH Cancer Genome Atlas Program through the Cancer Center Tissue Bank Core Facility.
3. AIM 3:
   a. The RTS-Smartstore DNA storage robotic system, within the Hussman Institute Biorepository is now fully operational and implemented into the Nautilus LIMs system.
   b. Adoption and development of the NCI-designated ca-Tissue for de-identified biospecimen management, cataloguing, tracking, and distribution with associated clinical data.
   c. Initiated integration of sample acquisition and tracking between the Genomics Institute and the Cancer Center Tissue Bank Core Facility.
   d. Initiated discussions with the CTSI Bioinformatics component for the interfacing of the BioResource specimen data with EPIC and the overarching Research Data Environment (URIDE).
4. AIM 4:

a. Implemented a prototype common consent form for patient enrollment within the Cancer Center Tissue Bank Core Facility to serve as a model for the larger enterprise-level BioResource initiative.
b. Implemented standard operating procedures for the procurement, processing, storage, and distribution of human samples in accordance with the NCI Best Practices guidelines.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

The BioResource team was involved in a UM CTSI sponsored two-day mini-conference focused on enterprise-level biospecimen consenting and electronic medical record data protections via Trusted Broker mechanisms, set up by Drs. Fiore and Goodman as part of the Ethical Integration sub-committee. These high-level discussions and working meetings are designed to provide a strong foundation for the BioResource component and the future research opportunities afforded to our UM community and the broader CTSI research community. This conference had representation from multiple CTSI institutions and served as a fantastic collaborative tool for our component. One result of the results of this meeting was the clear benefit for team members to join appropriate CTSA key function groups in the coming year.

F. PLANS FOR COMING YEAR

1. 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 UM CTSI BioResource.

2. Develop an initial "Virtual Storefront" tool for investigators across the UM medical campus to query de-identified information on currently available biospecimens.

3. Expand upon existing investigator-initiated and institutionally mandated collections, including the hiring of additional staff to accommodate increased usage of the BioResource as necessary.

4. Secure additional UM investigator contracts and external funding sources for BioResource sustainability efforts.

Miami CTSI Pilot & Collaborative Translational & Clinical Studies

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

B. GOALS

The main goal of the Miami CTSI Pilot and Collaborative Translation and Clinical Studies Component is to integrate pilot study activities across the Institution. This will be achieved by "federating" a wide variety of specialized and successful research funding programs from different UM Schools, Colleges, and Institutes under a single administrative umbrella.

1. AIM 1: Integrate existing pilot programs under one umbrella:
   (a) Build a system to facilitate marketing & outreach, automate electronic application & review, orchestrate award procedures, and conduct project evaluations; (b) Build scientific depth and interdisciplinarity across pilot research by sharing reports among Federation members to leverage, supplement, or exchange meritorious applications.
2. AIM 2: Enrich existing Pilot and Collaborative Funding Programs
   (a) Provide subsidized support from CTSI Components; (b) Broker mentorships and collaborations among awardees and expert co-investigators; (c) Fund highly innovative research aligned with CTSI mission.
3. AIM 3: Support talented investigators/projects important to CTSI.

C. CHARACTERISTICS

1. Action Plan for Year 1:
   a. AIM 1:
      i. Examine mechanisms and seek collaboration among university-wide internal funding resources.
      ii. Identify common and unique characteristics (eligibility requirements, application and review processes) associated with each funding mechanism.
      iii. Establish processes (e.g. RFAs, review templates) for funding mechanism standardization to establish the Federation for supplementing and exchanging meritorious eligible applications.
   b. AIM 2:
      i. Provide subsidized support from CTSI Components to improve the scientific quality of projects.
      ii. Broker mentorships and collaborations among awardees and expert co-investigators.
   c. AIM 3: The action plan to fund highly innovative research aligned with CTSI mission and support talented investigators/projects important to CTSI was as follows:
      i. UM-wide announcement of funding opportunities for projects using newly created RFAs.
      ii. Establish a multi-layered review process and formalize the award mechanism.
      iii. Fund highly innovative research aligned with CTSI mission
      iv. Establish a timeline for monitoring awardee progress.
2. Progress in Year 1:
   a. AIM 1:
      i. Began dialogue with leadership of all internal funding mechanisms to build the Federation: Provost Awards, Sylvester Comprehensive Cancer Center (SCCC), Scientific Advisory Committee (SAC), Glaser Awards, Developmental Center for AIDS Research (DCFAR), Interdisciplinary Team Sciences (ITS), Clinical Research Center (CRC).
      ii. Partnered with Information Technology Team (IT) to begin creation of automated application and review processes to harmonize and synchronize the CTSI and other award mechanisms.
   b. AIM 2:
      i. Generated RFAs and established application processes for the CTSI Components Services Credits and Pilots Awards. These were created based on established templates and guidelines used by internal award mechanisms, and appropriately modified to reflect the unique requirements of the Miami CTSI Pilot Awards: Culturalized health, health disparities, transformative and innovative interdisciplinary collaborations, and mentoring. The target applicants were: (1) Junior investigators

generating preliminary data for a peer-reviewed health-related federal grant; and (2) Senior investigators focusing on new programmatic approaches.

ii. Brokered mentorships and collaborations among awardees and expert co-investigators: (a) Identified established SCCC and DCFAR investigators as mentors for two Pilot awardees (Drs. S. Pochi and S. Kenya, (b) Supported training and mentoring opportunities for three underrepresented minority-trainees, (c) brokered collaboration between a Miami CTSI Pilot Awardee (Dr. S. Pochi) and University of Florida CTSI researchers.

c. AIM 3:

i. UM-wide announcement of funding opportunities with the following timeline:

10/09/2012	RFA posted	12/19-21/2012	Ethics Review
11/15/2012	Applications Deadline	12/20-22/2012	Programmatic Review
11/21-12/04	Invitations for Review	12/26/2012	Feedback to Awardees
12/12/2012	Reviews Deadline	12/27-01/04/13	Response from Awardees
12/05-12/2012	Biostatistics Reviews	01/07/2013	Awards Announced
12/18/2012	Panel Review Meeting		

Topics selected by the Advisory Board: substance abuse, obesity, STDs, maternal-child issues. Terms and conditions: appropriated up to $100,000 in direct research costs for one-year duration. Applicant Pool (N = 35 applications) from 15 Departments and across 3 Campuses: (a) Demographics: 20 women; 15 men; 5 known underrepresented minorities. (b) Rank: 18 Assistant Professor; 9 Associate Professor; 8 Full Professor; (c) Degree: 20 PhD; 12 MD; 3 MD/PhD.

ii. Multi-layered Review process:

- Selection of reviewers with expertise on the topics of the received applications. Most applications sent for review by CTSI Biostatistics Component
- Scoring of the applications according to the NIH scoring system, with additional criterion in alignment with the CTSI mission.
- Panel Review meeting (NIH Study Section format).
- Programmatic and Ethics reviews for top ten applications.
- Selection of Four projects for funding.
- Communication of full reviews and review panel summaries to all applicants.

Awarded Pilot Research Projects for 2012 -2013:

- Alessia Fornoni, MD/PhD, Medicine/Diabetes Research Institute*: "Personalized podocyte biology for the prediction of diabetic kidney disease in high risk populations."*
- Dileep Yavagal, MD, Neurology: *"Time window of intracarotid mesenchymal stem cell (IC-MSC) therapy in a large animal model of stroke*
- Subbarayan Pochi, PhD, Medicine/Sylvester Comprehensive Cancer Center (SCCC): *"Characterization of bioactive saponins with anticancer activity from Achyranthes aspera."*
- Sonjia Kenya, EdD, Epidemiology/General Medicine: *"Feasibility of Home-based HIV Rapid Testing (HRT) Among African-Americans in Miami."* Underrepresented minority PI.

iii. Established a timeline for quarterly reports: Awardees to submit 1-2 pages quarterly progress report and final report at the completion of the project.

iv. Provided subsidized support from CTSI Components: (a) Biostatistics for an ITS awardee (Dr. O. Bodamer), (b) Biostatistics, Community Engagement, and Novel Clinical & Translational Methods services for a planned center grant application (Dr. S. Daunert-UM-SPIRIT), (c) CRC services for a SCCC study (Dr. JM Goldberg).

v. Funded highly innovative research aligned with CTSI mission.

3. Opportunities, challenges, strengths, weaknesses and changes

a. *Opportunities*: (i) Multiple sources of expertise exist within UM for conducting transdisciplinary research. (ii) Multi-ethnic populations are available for examining the cultural health topics that are the primary mission of the Miami CTSI.

b. *Challenges*: (i) Balancing the efforts to form a federation of all UM pilot funding sources while respecting and supporting the decision-making structures in place within these entities. (ii) Forming the key participatory relationships with community stakeholders required to sustain long-term partnerships to facilitate research that is most relevant to the South Florida community served by the Miami CTSI.

c. *Strengths*: (i) Critical mass of scientific expertise available across UM campuses, (ii) Existing pilot programs with institutional support, (iii) Cadre of talented junior investigators including under-represented minority groups, and (iv) Multi-ethnic communities served by UM.
d. *Weaknesses*: (i) Lack of automation for communicating funding opportunities, (ii) Lack of uniformity in processes for reviewing, awarding, and monitoring progress.
e. *Changes:* (i) A formalized Federation of pilot funding sources being formed and maintained across university campuses, departments and centers. (ii) Automation of processes to enhance communications, decision making, monitoring and self-improvement is underway. These changes will be facilitated by an ongoing evaluation of "success metrics" within the Pilot Studies component.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1:
   a. Examined institutional pilot funding mechanisms and sought collaboration among university-wide internal funding resources.
   b. Developed RFAs and application forms to be used for Aims 2 and 3, in harmony with other internal funding mechanisms, while incorporating features unique to Miami CTSI mission.
   c. Introduced to IT personnel a request to create automated application and review processes
2. AIM 2:
   a. Brokered mentorships and collaborations among awardees, trainees, and expert co-investigators across CTSI, cancer Center and CFAR.
3. AIM 3:
   a. Completed the first round of funding processes, from RFA to award announcement in 13 weeks.
   b. Developed methods for monitoring progress on awarded projects**.**

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS: Planned for Year 2.

F. PLANS FOR COMING YEAR

1. AIM 1:
   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 Component.
   d. Reach out to Pilot Components of the CTSA Consortium to enhance the design of the Federation.
   e. Establish "Success Metrics" with Evaluation Component to monitor the Federation progress.
2. AIM 2:
   a. Work with and through pilot programs to strengthen their interdiscipilinarity to be consistent with CTSI theme of culturalized health sciences.
   b. Work with Education Component to enhance the mentorship and collaboration initiatives in place.
3. AIM 3:
   a. Refine RFAs to emphasize priority/focus areas in all communications.
   b. Form standing CTSI Pilot Studies Review Committee, made up of University/Community experts in basic and clinical science areas, as well as disparities, cultural Issues, and community-based methods. Community stakeholders will also be recruited to serve on the review panel.
   c. Monitor the progress of funded projects using matrices 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.

Miami CTSI Study Design and Biostatistics

A. PERSONNEL

Leadership: C. Hendricks Brown, Shari Messinger, J. Sunil Rao, Co-Directors
Other Personnel: Robert Duncan, Professor and Biostatistician; Evadnie Rampersaud, Research Assistant Professor and Quantitative Genetic Epidemiologist; Hua Li, Assistant Scientist and Biostatistician; Kaming Lo, Biostatistician; Maria Jimenez-Rodriguez, Core Administrator

B. GOALS

1. AIM 1: Establish University-wide Center for Statistical Sciences
2. AIM 2: Provide research design and biostatistics support to C/T investigators through the Biostatistics Collaboration and Consulting Core that leads to good science
3. AIM 3: Develop new biostatistical methods to move translational research forward
4. AIM 4: Provide educational programs to train the next generation of clinical researchers and biostatistical scientists to improve quality and quantity of research

C. CHARACTERISTICS

1. Overview
   a. AIM 1. The Division of Biostatistics was established in January 2010 under the direction of Dr. Rao as part of the process of building the CTSI, and has been the central organizational unit that is driving the establishment of the University-wide Center for Statistical Sciences. The Division is housed in the Department of Epidemiology & Public Health, serves as the home for research/graduate programs (MS and PhD) in Biostatistics, and provides collaborative support forC/T research through the Biostatistics Collaboration and Consulting Core, headed by Dr. Messinger. Division faculty members are engaged in teaching, as well as methodological and collaborative research.
   b. AIM 2. The Biostatistics Collaboration and Consulting Core (the "Core") is located in the Division of Biostatistics and operates as a cost center. The Core offers high quality statistical support for C/T research. The objective of the Core is to enhance the University's scientific mission by assuring appropriate planning and use of statistical methodology. The Core provides:
      i. Office hours for walk-in consultation; appointments for collaborative support for grant development, manuscript preparation, pilot development and review
      ii. Consultations and collaborations involve MS and Ph.D. level statisticians
      iii. Collaborations can be short term for specific research activities, or ongoing collaborations
      iv. State-of-the-art equipment to support biostatistical, epidemiologic, basic, and C/T research
      v. Miami CTSI has established guidelines for prioritizing resources: (1) junior investigators preparing NIH grants; (2) senior investigators focusing on new approaches; (3) investigators with funded studies that require supplements to achieve major breakthroughs.
   c. AIM 3. Both the Division (1.a above) and the Prevention Science and Methodology Group (PSMG) provide organizational support for this goal. The PSMG network, established 10 years ago and comprising more than 170 researchers and methodologists, conducts interdisciplinary methods presentations through weekly grand-rounds conference calls and facilitatesmethodological development and application in leading edge research nationally. Dr. Brown heads this group, and Dr. Messinger has joined PSMG's steering committee so that it can address the Miami CTSI agenda for developing translational biostatistics research. This Component has also created a small grant program to stimulate cross-school collaborations in methodological development.
   d. AIM 4. The Division of Biostatistics, the Core, and the PSMG provide support for this goal.

2. Action Plan for Year 1:
   a. AIM 1:Continue to develop working groups across campuses. Host brainstorming sessions to facilitate working group formation. Widen the net of quantitative seminars. Advertise seminars more widely across campuses. Interface with the Center for Computational Sciences as a catalyst.
   b. AIM 2: Continue to provide statistical support for all stages of research across campuses. Increase support for biostatistics support particularly for NIH grant submissions, funded pilot studies, and new programmatic approaches by senior investigators.
   c. AIM 3:Fund pilot quantitative methodology grants from around the University. Develop new software modules as translational deliverables. Catalyze new collaborations for methods development.

d. AIM 4:Expand doctoral level Biostatistics coursework by 6 courses in 2013. Increase the number of Ph.D. Biostatistics students by 4 in FY14. Continue to develop and host cross-disciplinary seminars and workshops e.g. seminars from the Marine School, Economics, Engineering, predictive modeling one week workshop. Continue to offer Biostatistics Clinics and Roundtables through the Core. Engage Biostatistics Ph.D. graduate students in Biostatistics Core office hours and quick consultations as well as providing educational opportunities to the research community.

3. Progress in Year 1

a. AIM 1: We are developing the business model for the Center for Statistical Sciences that will allow us to sustain a University-wide home for statisticiansacross the university's three campuses.

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

c. AIM 3: We are currently developing a proposal with collaborators from Harvard's CTSI (Dr. Maggie Alegria) and the University of Chicago (Dr. Robert Gibbons) that would lead to biostatistical and psychometric advances in extending computerized adaptive testingto diverse populations. Computerized adaptive testing provides great savings in time and increases precision of assessing symptoms and risk factors, but is exceptionally labor intensive and not easily translated to different languages. We are proposing an adaptive version of this approach that can be used to develop a Spanish version to measure depressive, anxious, and bipolar symptoms in primary care.We are also developing new biostatistical approaches to understanding what we call *scientific equity*. In relation to health equity and health services equity, scientific equity refers to maximizing the scientific knowledge that can be applied to ameliorate disparities. In relation to culturalized health, scientific equity requires a strategic approach to collecting sufficient epidemiologic, effectiveness trial, and implementation study data on minority populations, then using state of the art methods for synthesizing these data across studies.
Four Pilot Projects: (1)One seeks to develop new biostatistical approaches to account for overlap in published meta-analyses, representing a major technical challenge to summarizing intervention effectiveness across diverse populations.(2) The second looks to develop user-friendly software for implementing random survival forests which is a non-parametric technique for fitting high dimensional survival models that allows complex interactions between the predictors. (3) Another project will develop new statistical methods for the identification of long noncoding RNA pathways, techniques that will be used to analyze brain tumor samples from Hispanic and Caucasian patients at UM. (4) The fourth pilot project will develop methods for rotation to a partially specified target matrix in exploratory structural equation modeling with the goal of identifying how many targets should be used in practice. The application area of interest is the multicultural study I COPPE which aims to develop a framework for wellness through a valid measurement instrument for 6 important domains of individual well being: community, occupational, physical, psychological and economic (I COPPE).

d. AIM 4. Dr. Messinger with the Core staffare developing new educational programs for the C/T community including monthly biostatistics clinics and weekly roundtable sessions. Core faculty and staff are now attending presentations of the PSMG and the Division of Biostatistics.The Ph.D. program in Biostatistics currently has 7 students that have completed their first year of studies, and we are in the process of accepting 3applicants for the next cohort..A suite of advanced courses (6 in total) are currently being developed for next school year, including Bayesian Data Analysis and Bayes Computing, Statistical Analysis of Clinical Trials, High Performance Computing, Advanced Statistical Theory, Spatial Data Analysis and Advanced Survival Analysis.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1: Two interdisciplinary seminars, which were attended by statisticians and quantitative scientists across the University's three campuses were held. This is in addition to the 5 regular biostatistics. These have led to some cross-pollination across individuals from around the University. More indirectly, there have been 3 pilot statistical methodology grant proposals that have been funded by the CTSI that involve collaborators across the campus that were not previously working together.

2. AIM 2: A total of 57 projects have been supported during the Miami CTSI reporting period. We have identified at least 3 Abstract Preparations, 24 Data Analyses, 10 New Grant Applications, and 12 Manuscript Preparations that have derived from these activities. (Appendix 2)

a. A total of twenty-nine consultations for new projects have taken place. (Appendix 3)

b. Pilot Projects: There were 10 pilot projects considered for CTSI pilot awards that were reviewed by the Component. Three of these pilot projects were awarded by the Miami CTSI and are receiving biostatistics support. (Appendix 4)

3. AIM 3.
   a. Statistical Programs: For integrating findings from mediational analyses across multiple randomized trials, we have developed an R program for this problem that is now being used in evaluating the impact of parental communication on Hispanic adolescents' drug use.
   b. Statistical Methods Papers: We have five submitted papers that involve innovative statistical methods for translational research. (Appendix 5)
   c. Statistical Scientific Presentations: We presented to 4 scientific communities this year on biostatistical approaches to translational research. (Appendix 6)

4. AIM 4.An educational series for the C/T community and biostatistics facultywas developed and implemented by the Core and Division of Biostatistics. (Appendix 7) Additionally, a T32 application was developed and submitted for a training program relating to issues in quantitative health disparities research (PI: Messinger and Rao).

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Dr. Shari Messinger is 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

F. PLANS FOR COMING YEAR

1. AIM 1. We will begin development of a University-wide Center for Statistical Sciences with the intent of creating what will one day be a leading research node among national networks in translational quantitative methods development. The Center will serve as a catalyst for methods development in translational science to transform the way research is done, and will serve as an umbrella structure for quantitative researchers from disciplinesacross the University. The Center will foster cross-pollination of ideas through regular brain-storming meetings and bring together individuals who may not otherwise work together. In addition, the Center will host national workshops and regular seminars as well as facilitate a richening of educational opportunities for graduate students from around the University. Development of the proposed Center will entail 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. AIM 2.In the coming year, the Core will continue to provide research design and biostatistics support fostering research productivity and leading to good science. Core resources will be prioritized towards culturalized health sciences and health disparities research, in line with the Miami CTSI mission. Support will be provided through office hours, collaborative support, dissemination of findings through manuscript preparation, and in thesupport of pilot projects and other Miami CTSI funding mechanisms. Biostatistics Core faculty and staff will engage in activities of the proposed Center, fostering communication and increasing opportunities for methods research. Core faculty and staff will also engage in educational opportunities offered through the proposed Center. Productivity can be evaluated by consultations provided to C/T investigators and number of projects supportedthat are submitted for publication in top tier journals or for extramural funding.
3. AIM 3. 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. We, along with our collaborators, plan to submit an NIH application to develop the biostatistical and psychometric methodology for extending computerized adaptive testing to minority populations. This method would identify items that display differential item functioning as well as different underlying psychometric structures. We plan to submit this as an extension of measuring depressive, anxious, and bipolar symptoms in a Spanish speaking population as a model that can be generalized to other medical conditions and populations.
4. AIM 4.Quantitative health disparities research is a growing field and we anticipate that the proposed Center will allow UM to further deepenour foothold in this arena. 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. 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.

Miami CTSI Regulatory Knowledge and Support

A. PERSONNEL:

Leadership: Jonelle E. Wright, PhD, and Margaret Fischl, MD

Other Personnel: TBA: Research Subject Advocate, Associate Research Subject Advocate, Research Subject Advocate Coordinator/QI Specialist, and Regulatory Quality Improvement Specialists (2)

B. GOALS:

1. AIM 1: Provide consultation regarding regulatory requirements in research protocols
2. AIM 2: Build and operate repository of investigator-focused clinical research regulatory tools, templates, and training
3. AIM 3: Establish and implement a DSMP (data & safety monitoring plan) resource and research participant advocacy service in CTSI study protocols
4. AIM 4: Improve safety and efficiency of C/T research through regulatory knowledge and support process improvements, including tools, best practices, and available resources/expertise disseminated by CTSA Consortium (examples: IRBshare, REDCap, workforce development for research professionals)

C. CHARACTERISTICS

Co-Directors Wright and Fischl work together to build the Miami CTSI Regulatory and Support Component's programs and services as articulated in the Component's Specific Aims. They assure close collaboration with other CTSI Components as appropriate to the tasks at hand. Component Director(s) meet monthly with the CTSI Administrative Leadership Team, weekly with the Research Cabinet, monthly with the other CTSI Component Directors, and every two weeks with the Director of RSQA to keep abreast of institutional progress and closely align Component activities with related University programs.

1. Action Plan for Year 1
   a. AIM 1
      i. Hire, orient, and train Component staff.
      ii. Initiate consultation services.
   b. AIM 2 –Engaging appropriate programs, including the Office of Research and Innovative Medicine, start inventorying UM regulatory knowledge-related resources, tools, templates, and information.
   c. AIM 3 – BuildDSMP framework.
   d. AIM 4 –Review CTSA Consortium tools/resources, attend their workshops to learn about them.
2. Progress in Year 1

   The Regulatory Knowledge and Support Component realized a strong start in its efforts to develop services and infrastructure for process improvement in clinical and translational research. Component Directors offered expert consultation, advice, and information resources regarding human protections and adhering to regulatory guidelines in University research programs, institutional research oversight activities, and individual study protocols managed by investigators and trainees. We can now report success in initial efforts to facilitate University adoption of CTSA Consortium tools that advance process improvements in the administration of clinical research. In the following we list activities for Year 1.
   a. AIM 1
      i. In collaboration with Pilot and Collaborative Studies, Research Ethics, and Research Training Components, reviewed and advised Pilot Grant and K12 grant applicants, respectively, for regulatory requirements and human subjects' issues.
      ii. Provided consultation on regulatory requirements to investigators and trainees.
      iii. Planned with Research Navigator strategies for assuring human subjects' protections and adherence to regulatory guidelines in CTSI-related research activities.
   b. AIM 2
      i. In collaboration with the CTSI Research Navigator and Alianza, Research Ethics, and Research Training Components, initiated cooperation with Office of Regulatory Support and Quality Assurance to inventory and consolidate regulatory tools, templates, and training resources.

ii. In collaboration with Miami Center for Research Participation & Partnership, Research Ethics, and Research Training Components, hosted a day-long planning meeting represented by four CTSAs to identify curriculum content for Clinical Research Coordinator training program to be developed for presentation via CITI IT platform.
iii. To publicize Component services, presented poster of Regulatory Knowledge & Support Component goals, programs, and resources at CANESEARCH.

c. AIM 3
i. Established DSMP framework.
ii. Initiated work on IT system improvements to accommodate DSMP activities on CITI platform.
iii. Developed and submitted to HR for approval RSA and RSA Associate job descriptions.

d. AIM 4
i. Obtained Research Cabinet approval for IRBShare and worked with RIM, Human Subject Research Office, and legal counsel to adopt and sign contract for it.
ii. Worked with Human Subject Research Office to improve eProst system.
iii. In collaboration with Research Ethics Component, helped host a 2-day meeting represented by five CTSAs to address Trusted Broker Systems and Universal Consents and development of relative standards and best practices.
iv. In collaboration with medical center representative, institution legal counsel, and Research Ethics, BioResource, and Biomedical Informatics Components, initiated work on Universal Consent to be operationalized in collaboration with Trusted Broker System.
v. Developed, presented to Research Cabinet, and submitted to HR for approval a section on Regulatory Compliance/Responsible Conduct of Research/Human Subjects' Protections to bea required element in all research family job descriptions.
vi. Developed and obtained Research Cabinet approval for Clinical Research Coordinator Career Ladder framework that included requirements for Regulatory Compliance/Responsible Conduct of Research/Human Subjects' Protections activities and training.

3. Opportunities, Challenges, Weaknesses, Strengths, and Changes – A centralized resource of regulatory knowledge and support is essential for assuring consistent standards in human protections and adhering to University policy and state and federal regulations in research. Given that the Institution had no formal service to offer individualized consultation to researchers needing help in this important area, we are working to fill an important void. Two areas that we pay particularly close attention to are navigating complex regulatory standards and establishing quality services/practices to assure participant safety and advocacy, scientific integrity, and responsible conduct of research.
The primary challenge we face is the fact that University research programs and departments have functioned independently for such a long time that investigators feel high levels of ownership and strong commitment to doing things the way they always have.System-wide buy-in to consolidating and harmonizing services, resources, tools, and best practices is slow. Just learning about and gaining access to tools, templates, etc. used successfully in work with Miami's uniquely diverse populations has proved challenging in the absence of a central repository.
A major strength that we will take advantage of going forward is our ability to use the world-wide CITI program platform to a) post training information for easy access by investigators and b) develop and provide access, in real-time, study-specific DSMPs. Another strength realized is the expertise, practical experience, and extensive network of experts each of our Component Co-Directors hold in this area.
Last, given that we are in our inaugural year, no changes were made in the Component.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1 – We have successfully initiated our consultation service. Demand for it is growing fast.
2. AIM 2 – Efforts to build our repository of regulatory-related tools, templates, procedures, and best practices, while labor intensive, will prove of value to researchers not previously having access to such.
3. AIM 3 – We have developed the framework for our unique approach to DSMP that, once operationalized, will transform how research professionals make day-to-day decisions regarding priorities in study participant safety and advocacy, scientific integrity, and adhering to standards of responsible conduct of research.

4. AIM 4
   a. REDCap has been instituted at the University and is fully operational, facilitating data collection by many investigators and research administrators.
   b. UM IRBShare contract has been finalized and signed, ready to expedite IRB approval processes for future collaborative/multisite studies.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Participates 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.

F. PLANS FOR COMING YEAR

1. AIM 1
   a. Finalize hires for regulatory staff.
   b. Continue to provide human subjects' safety, DSMP, and regulatory-related consultation.
2. AIM 2
   a. Continue inventorying UM resources to identify and consolidate best practices/templates for human subjects' safety, DSMP, and adherence to regulatory guidelines.
   b. MaintainCTSI, RIM, and RSQA collaboration in building repository of human subjects' safety, DSMP, and regulatory-related tools, templates, and best practices.
   c. Initiate operations of repository.
3. AIM 3
   a. Finalize DSMP framework.
   b. Hire, orient, and train RSA team.
   c. Start to build operational components of DSMP program.
4. AIM 4
   a. Keep abreast of and record CTSA Consortium resources appropriate for adoption at UM.
   b. Introduce new developments from CTSA Consortium Continue to appropriate UM stakeholders.
   c. Initiate process improvement activities as appropriate.
   d. Continue work on Career Ladder and job descriptions.
   e. Continue work on Trusted Broker System and Universal Consent.
   f. Continue work on Clinical Research Coordinator training curriculum.

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

A. PERSONNEL

Leadership: Myles Wolf, MD, Director; Tracie Miller, Director;JoNell Potter, Director
Other Personnel: Joanne Krasnoff, Senior Manager for Research Support

B. GOALS

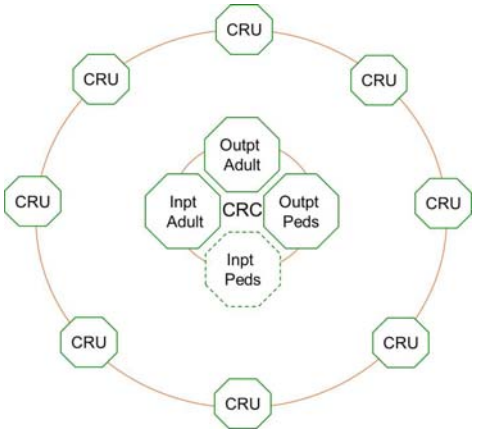
1. AIM 1: Establish a Network of centralized, affiliated locations for patient-oriented research
2. AIM 2: Create a centralized operational core to enhance education, training, competency, career development, and productivity for clinical research support staff
3. AIM 3: Enhance infrastructure to ensure highest ethical and regulatory standards and promote scholarly activity while accelerating the pace of research translation

C. CHARACTERISTICS

1. Organization

Performance of the highest quality clinical and translational research and training requires state-of-the-art clinical research resources (facilities, including well-equipped space to perform inpatient and outpatient studies), services (pharmacokinetic studies, specimen processing, etc.) and know-how (highly knowledgeable and skilled clinical research professionals including research nurses and clinical research coordinators). Developing this capability is the primary goal of ¡Alianza!

¡Alianza!consists of core adult and pediatric Clinical Research Center (CRC) Sites, and a collection of additional Clinical ResearchUnits (CRU) where clinical research is also performed across campus (**Figure**). The CRCs are fee-for-service facilities available to all investigators in the University. These facilities provide space, staffing and services to conduct clinical research study visits. The CRCs ensure clinical certification and licensure of all staff, and oversee calibration and maintenance of all equipment. Between July 2012 and March 2013 the adult CRC provided clinical research services to 50 protocols and 1569 study visits, representing 17 different clinical departments at the medical school. Among these protocols, 3 were led by K-awardees, including one minority faculty member, and 6 were community-based protocols serving underserved minority populations. The Pediatric CRC provides clinical research services to 52 government-funded, industry-related, or investigator initiated protocols across the Department of Pediatrics. This collaboration has resulted in over 95 publications in peer-reviewed journals over the interval. Due to the resources and support from the Pediatric CRC, the Department of Pediatrics continues to rank among the top funded programs at the Miller School of Medicine.



The stand-alone CRUs which also perform clinical research are staffed with a combination of study coordinators, regulatory staff, research assistants, nurse coordinators, etc. These sites are predominately independent research teams that historically have performed all aspects of their own clinical research protocols from IRB submission through recruitment of participants, and study assessments in a clinic setting or a dedicated research facility. A major goal of ¡Alianza! is to bring together leadership of all of these clinical research sites to define standards for good clinical research practice, agree to a set of institution-wide standard operating procedures for clinical research, and harmonize our operations under ¡Alianza!.

2. Progress and opportunities

a. AIM 1: Establish a Network of centralized, affiliated locations for patient-oriented research

The first step in establishing ourNetworkof participating clinical research sites has been to convene leadership of individual sites to develop and draft universal clinical research standard operating procedures.The core CRCs and the leading CRUs where clinical research is also performed across campus and in the community have met regularly (quarterly) to work collaboratively to draft these universal clinical research standard operating procedures. Through this initial committee work, an integral group understanding of why and how we must move to create this Network of centralized, affiliated locations is crystallizing. We will capitalize on this team momentum as we continue

operational standardization amongst these sites in year 2. Our goal is to complete this process of developing standardized operating procedures during year 2 of this award.

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

A highly knowledgeable and skilled clinical research support staff is critical to a successful clinical research enterprise. ¡Alianza! is developing a clinical research training curriculum as well as mentoring opportunities for our clinical research support staff. This work is being performed in collaboration with the Educational component of the CTSI and the Universityof Miami Miller School of Medicine Office of Regulatory Support and Quality Assurance.

In addition, ¡Alianza! hosts meetings of the Network of Clinical Research Professionals. This new organization provides a portal for enhanced clinical research communication and Networking among the entire University's clinical research support staff. Its goal is to link education, training, core research competencies and empowering this group helps to maintain a high "esprit de corps" that will improve work quality and to provide a source for continue feedback to the Miami CTSI leadership from the "front lines" of clinical research.

To recognize the efforts of our clinical research support staff, enhance their research core competencies and stimulate their career development, ¡Alianza! proposed a 'Career Ladder' for Clinical Research Professionals. The Career Ladder will be a means to establish clearly defined milestones for clinical research support staff to increase their skill sets, achieve higher levels of research responsibility and lay out incentives to greater compensation. The overarching goal is to improve the quality and consistency of performance of tomorrow's clinical research support staff. This exciting proposal has already received the preliminary support of the Vice Provost for Research and the Miller School Executive Dean for Research, and is currently under review by our office of Human Resources.

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

Working in collaboration with the Regulatory Knowledge and Support, Clinical Research Ethics, we are ensuring that the standard operating procedures we institute across our Clinical Research Network adheres to current regulatory and ethical standards.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1: Establish a Network of centralized, affiliated locations for patient-oriented research
   a. Established a committee of Directors from CRCs and CRUsto develop standard operating procedures for clinical research across the Network
   b. Developed a list of universal clinical research standard operating procedures for clinical research sites across the Network
   c. Developed a plan for anintegrated hospital-based inpatient/outpatientclinical research sites
   d. Developed a preliminary plan for a certification process of free-standing research sites across the Network

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

Together with the Education and Regulatory components of the CTSI and the Office of Regulatory Support and Quality Assurance, we have:

   a. Developed an institutional-specific clinical research support staff workshop
   b. Established a collaborative committee to develop research coordinator education and training
   c. Developed Clinical Research Coordinator education & training outline
   d. DevelopedtheClinical Research Professionals Career Ladder that is currently under review
   e. Continued regular Network of Clinical Research Professionals meetings

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

   a. Research Stimulus Package: We instituted a subsidy to offset costs incurred by investigators using ¡Alianza! resources. Our goal is to stimulate research and utilization of CTSI-supported sites.

b. Junior Faculty Research Award: We provide support to offset costs incurred by promising junior investigators by issuing credits for clinical research services in the Network. Awards are granted based on peer-review with priority to those currently supported by career development awards.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Developed an outline for standardized clinical research coordinator education and training curriculum in collaboration with Southern California CTSA, Harvard CTSA,and University of Cincinnati CTSA
2. Actively participating on taskforce of the Regulatory Key Function Committee(KFC) to create standardized clinical research coordinator education and training curriculum
3. On-going communications with the University of Florida and University of California San Francisco CTSIs to learn and exchange information with successful clinical research sites
4. Participated in Clinical Services Core, Regulatory, and EducationKFCteleconferences

F. PLANS FOR COMING YEAR

¡Alianza! has begun the long-term transformational process to improve the quality and efficiency in our clinical research enterprise, and contribute to the national CTSI consortium efforts. We are excited to continue our progress and move forward on the following initiatives in year 2:

1. AIM 1: Establish a Network of centralized, affiliated locations for patient-oriented research
   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 adultCRC 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. AIM 2: Create a centralized operational core to enhance education, training, competency, career development, and productivity for clinical research support staff
   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 CTSAs and the Regulatory KFC (with Education and Regulatory components)
   c. Continue hosting Network of Clinical Research Professional gatherings

3. AIM 3: Enhance infrastructure to ensure highest ethical and regulatory standards
   a. Complete and implement regulatory-compliant, universal clinical research standard operating procedures 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 to address through CTSI leadership
   c. Develop and implement¡Alianza!-specific Leadership Operations Committee and Scientific Advisory Committee
   d. Renew Junior Faculty Research Awards program
   e. Continue participation in CTSA consortium activities

Miami CTSI Research Education, Training, and Career Development
(Comprehensive Research Education and Translational Training Environment (CREATTE))

A. PERSONNEL **Leadership:** Neil Schneiderman, Co-Director; Gwendolyn Scott, Co-Director
Other Personnel: Carlos Sandoval, Program Coordinator

B. GOALS

1. AIM 1: Provide an institutional home for research education, training, mentoring and career development in clinical/translational science
2. AIM 2: To expose a broad spectrum of students, trainees, faculty, research staff, and community collaborators to the principles of translational science and the standards of good practice in clinical research.
3. AIM 3: To develop degree-granting and formal early career mentored programs that will expand and diversify the research workforce, with a particular focus on addressing health care disparities and culturally appropriate research methods.
4. AIM 4: To create mentoring programs that maximize advancing trainees toward academic careers through: (a) intensive mentoring, (b) close monitoring of trainee progress and (c) implementing retention strategies; and (d) tracking and evaluating the quality and outcomes of the graduates of these programs

C. CHARACTERISTICS

1. Overview: The Comprehensive Research Education and Translational Training Environment (CREATTE) has as its mission to provide transformational, University-wide, transdisciplinary, culturalized health science education and career training.

2. Significance: To understand the context within which CREATTE operates, it is necessary to recognize three of the major transformational currents sweeping through Miami-Dade County with its population of about 2.5M: cultural diversity, economic and health disparities, and need for access to quality public health care (over 700,000 persons are uninsured).

3. Progress:
   a. AIM 1: Provide an institutional home for research education, training, mentoring and career development in clinical/translational science
      i. The first step in establishing our home for research education is to develop and create an active CREATTE operational committee, followed by the hiring and training of the CREATTE administrative assistant who provides support to all CREATTE activities, our operational committee members, and our directors..

   b. AIM 2: To expose a broad spectrum of students, trainees, faculty, research staff, and community collaborators to the principles of translational science and the standards of good practice in clinical research
      i. Developed ethics training for research staff, graduate students, postdoctoral research fellows, early career investigators, etc.
      Coordinated with ¡Alianza! and University of Miami Office of Regulatory Support and Quality Assurance to develop training and certification of Clinical Research Coordinators and staff, including Bootcamp; 17 short courses which are in the process of being placed online utilizing the CITI online platform, to address issues such as informed consent, protocol compliance, and other key clinical research areas; and an internship/mentoring component.

   c. AIM 3: To develop degree-granting and formal early career mentored programs that will expand and diversify the research workforce, with a particular focus on addressing health care disparities and culturally appropriate research methods.
      i. Established the coursework required and enrolled the first class of students for the Masters in Clinical and Translational Science

ii. Enrolled Early Career Investigators into the K12 program.
iii. Involved career, scientific and clinical mentors into these programs

d. AIM 4: To create mentoring programs that maximize advancing trainees toward academic careers through: (a) intensive mentoring, (b) close monitoring of trainee progress and (c) implementing retention strategies; and (d) tracking and evaluating the quality and outcomes of the graduates of these programs
   i. A University-wide committee has been formed, led by Zafar Nawaz, Ph.D., to develop Ph.D. curriculum concentration and mentoring program in Clinical and Translational Research, in which specific C/T coursework would be required.
      - Meetings have been held between the CREATTE co-directors and Program in Biomedical Sciences (PIBS) graduate training directors to begin developing Clinical and Translational concentrations in what are now exclusively basic science Ph.D. programs. This is a critical first step in the development of C/T tracks for basic science Ph.D.s.
      - The Component has met with Institutional stakeholders to begin discussions around the selection and role of mentorship for the Ph.D. curriculum, which would include three types of mentors: career, scientific and clinical.
   ii. Development is underway of a Career Mentoring Course.

4. Opportunities, challenges, strengths, weaknesses and changes:
   a. *Opportunities*: (i) Structure education and mentorship processes to make them proactive and available to all the community. (ii) Use of IT tools to develop and coordinate education activities across the University, and with the goal of laying the foundation for transformational research.
   b. *Challenges*: (i) Budget limitations, (ii) Limited time of academic faculty.
   c. *Strengths*: (i) Communication across other components to strengthen education and mentorship. (ii) Knowledge and depth of experience in this area.
   d. *Weaknesses*: (i) Resource limitations. (ii) Reliance on other Institutional groups.
   e. *Changes:* Better integration of Bootcamps and Masters in C/T science into Miami CTSI's CREATTE component.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1:
   a. Activated the CREATTE operations committee.
   b. Hired and trained the CREATTE administrative assistant.

2. AIM 2:
   a. The application process for the K12 program was developed, an RFA issued, NIH-style reviews completed, two K12 awards made, and RFA for the FY02 awards issued. Focus on minority health disparities. Complete reports can be found in the Training Individual Progress Report section. The K12 scholars that have been appointed this year include:
      i. John Goldberg, MD, Assistant Professor of Pediatrics, Project Title: *Novel Dendritic Cell Vaccination and Co-Stimulation in Brain Tumors*
      ii. Ivan Gonzalez, MD, Assistant Professor of Clinical Pediatrics, Project Title: *Evaluation of the Immunosenescence in Perinatally HIV and Behaviorally HIV Infected Cohorts*
   b. Bootcamp has been carried out annually 2010-2012 to instruct early career investigators (MD & PhD Fellows and Junior Faculty) about opportunities available in Clinical and Translational Science. We enroll 100 participants for each Bootcamp. Focus on minority health disparities in collaboration with the Community Engagement Component

3. AIM 3:
   a. The Master's Program in Clinical and Translational Science has been initiated. The first 7 students have completed two semesters of the program. All students have doctoral degrees and are thus obtaining advanced training to increase C/T research skills

4. AIM 4:
   a. CREATTE, ¡Alianza! and University of Miami Office of Regulatory Support and Quality Assurance are working with the Vice-Provost for Research to develop a program leading to the training and certification of Clinical Research Coordinators and research staff.

   b. Conducted Mentoring workshop on "Resubmissions to the NIH" in collaboration with SEEDS (Scientist and Engineers Expanding Diversity and Success) and the Office of Research and Innovative Medicine)

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

Attended Education and Career Development Key Function Committee meeting.

F. PLANS FOR COMING YEAR

1. AIM 1:
   a. Continue strengthening infrastructure for research training and education through building of collaborative relationships with Miami CTSI Components and Institutional stakeholders.
      - Continue training personnel to provide research education navigation assistance to internal and external clients.
      - Continue to promote education on culturalized health sciences, and a focus on underrepresented minorities.

2. AIM 2:
   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 presentation on Clinical Translational Science.

3. AIM 3:
   a. Enroll second class in Masters of Clinical and Translational Science and select mentors.
   b. Become more involved with the Education and Career Development Key Function Committee.

4. AIM 4:
   a. Develop one or more mentoring courses.
   b. 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.
   c. Monitor K12 program and provide extensive mentoring.
   d. Develop content for and organize a workshop focusing on the development of T32 programs in Clinical and Translational Science.

Miami CTSI Community Engagement and Cultural Diversity

A. PERSONNEL:

Leadership: Olveen Carrasquillo, Director; Erin Kobetz, Co-Director; Guerda Marie Nicolas, Co-Director

Other Personnel: Victoria Mitriani, John Ryan, and Brendaly Rodriguez

B. GOALS: The goals on the Community Engagement and Cultural Diversity Component (CECD) is to foster mutually beneficial relationships between the CTSI and our community and provide important infrastructure and resources for CTSI investigators and trainees in the conduct of community based research. Within that context the CECD defines Community Engagement as the intersection of complementary efforts of members of the lay community, community organizations, health practitioners and medical and public health researchers to improve health.

1. AIM 1: Foster long-term participatory academic-community bidirectional collaboration, assist investigators in conducting community-based research
2. AIM 2: Develop a resource center for investigators seeking advice and expertise in research with diverse communities
3. AIM 3: Training programs in Community Based Participatory Research (CBPR) and health disparities research
4. AIM 4: In consultation with the Project Officer, we droppedAim4 on development of a practice based research network.

C. CHARACTERISTICS

1. Organization:
   a. The CEDC continues to work with other CTSI components to achieve our goals. We participate in the monthly Operational Leadership Meetings, in monthly meetings with the CTSI administrative leadership, and meet weekly with our staff. Our core has also presented to the School of Medicine's Research Cabinet and to the CTSI Scientific Advisory Group.
   b. The CEDC has completed the hiring of our coordinator, Ms. Brendaly Rodriguez, MA. Ms. Rodrigues was formerly project manager of the NCI U54 South Florida Center for Cancer Reducing Health Disparities and prior to that community outreach coordinator for the Miami Field Center of the NHLBI Hispanic Health Study. She is also vice- president of the Latino Caucus of the American Public Health Association. We are also finalizing the hiring of our first Community Research Associate. Ms. Cynthia Lebron, who was previously a Community Health Worker in our NHLBI R01 Miami Healthy Heart Initiative. We also hired a graduate research assistant to help in establishing our Component's Resource Center.
2. Progress
   a. Aim 1: We continue to have our ongoing meetings (most every two months) with our four local community advisory boards (Little Haiti, Hialeah, Liberty City and South Dade). We had seven faculty members interested in community input into their projects present to the CAB meetings for community feedback. We also continue to provide consultation to investigators seeking assistance and our mentoring in community based research projects. As an example, eight proposals submitted for CTSI pilot or K funding received direct input from our core in the development of the proposal's research plan. We also continue our monthly "Whats up Doc?" seminar where UM faculty go to various community centers in Overtown presenting in lay language and answering questions on various health topics. With respect to provider outreach, we have had several group meetings with community-based physicians in the Hialeah area to develop more effective and bilateral collaboration with UM the University in both research and data sharing through our EMR interface.

      Not surprisingly, to foster a bi-directional academic-community relationship, much work also needs to be done to transform the Institutional culture in relationship to our beliefs about the role of the community in clinical and translational investigation. We have began this process by presenting and

demonstrating participatory processes to our Operational Leadership Group and the Scientific Advisory Group.

b. AIM 2: We are creating a profile format page that will be used to collect information about different researchers at UM who are conducting community based research and or research with culturally diverse communities. The graduate student will be combing through the website of each of the schools/department for faculty members who have published or presented in the areas. 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.

c. AIM 3: This September we collaborated with CTSI in the annual CTSI research bootcamp for postdoctoral research fellows and junior faculty. A half day in the week long bootcamp was used for training in health disparities research and community based participatory research. In addition, over 20 students took a full semester CBPR course in the Fall. Together with our Component faculty from the Schools of Nursing and Education this Spring semester we are having four seminars on community engaged health disparities research at the University's Gables (non-medical) campus. Component faculty also played key roles in the annual National Meeting of the Latino Medical Student Association held in Miami in March, 2013 where our component's faculty led in workshops on clinical research for minority medical students, health profession careers seminar for high school students, and judges in the scientific poster session.

D. MAJOR ACCOMPLISHMENTS AND IMPACT

1. AIM 1:
   a. We have been working with UM's largest clinical partner Jackson Memorial Hospital on a development a comprehensive research engagement framework for all UM sponsored research at JMH based on fostering bidirectional mutually beneficial research. A preliminary draft of the agreement was prepared and is being reviewed by the School of Medicine's Executive Dean.
   b. We were able to have 10 community partners attend and present posters at the CTSI CaneSearch Obesity Symposia alongside posters by UM scientists.
   c. We a key role developing UM's Community Health Needs Assessment as required under the Affordable Care Act.
2. AIM 3:

   Our trainee, Dr. Sonja Kenya was selected as one of the four initial CTSI pilot trainees. Her project focuses on use home based Rapid HIV testing as a means to increase HIV screening in underserved African-American communities, one of the priority areas highlighted by the CTSI Community Advisory Board.

   Medical Student Hansel Tookes, building on a project showing high rates of dirty needles in Miami due to lack of needle exchange programs (another CAB identified community priority), has spearheaded a medical student led State-Wide campaign to write and introduce House and Senate bills in FL allowing for needle exchange programs in the state. This initiative has garnered 500 hours of service from the Florida Medical Association, the full support of our University's lobbyists, support from over 10 State-wide organizations, Bills introduced in the State House and Senate and committee hearings.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

1. Participate in the monthly Key Function Committee conference Calls

F. PLANS FOR COMING YEAR

1. Now that our staff and organizational structure is in place, we will begin to focus on process areas that will result in increased input, consultation and participatory engagement of community stakeholders in ongoing research at UM, including our planned seminars series, CRA serving as a two way interface between community groups and investigators, and planned dissemination platform. Perhaps even more important is our University initiative to change the University culture with regard to how research in the community should be conducted: collaboratively. Our Investigators' culture has been one of

investigators writing grants without community consultation, and then expect the community to respond to a funded grant. We are systematically tackling the University's culture.

2. We will continue to work with CTSI executive leadership in transforming the perspective of investigators to increasingly consider short term impact their research will have on improving the health of our local community and continue to have the CTIS prioritize such research not only among CTSI faculty but also throughout UM. This includes increasing number of projects at UM with focus on racial and ethnic disparities in health and health care and those that include CBPR principles as part of their approach and focus.
3. Deploy the initial version of our resource center for culturalized health research

Miami CTSI Tracking and Evaluation

A. PERSONNEL

Leadership: Sara J. Czaja, Director; Margaret M. Byrne, Co-Director
Other Personnel: Sankaran Nair, provides technical and data support

B. GOALS

Overall Goal and Specific Aims

The primary goals of the Evaluation and Tracking Component are to: ensure that the mission of the CTSI is achieved, resources are distributed effectively and equitably, and the CTSI component services are appropriately configured, accessible, and utilized efficiently; and to measure the impact of the CTSI on clinical and translational research activities at the University of Miami. A unique feature of the evaluation component is the inclusion of evaluation research aimed at identifying innovative evaluation strategies and processes and factors that impact on the efficiency and effectiveness of CT research. To achieve these objectives the specific aims of our Component are to:

1. AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its components;
2. AIM 2: Conduct a rigorous and on-going evaluation of the CTSI and its components to:
   a. Identify structures, services and programs that are effective and those that are in need of improvement
   b. Evaluate the impact on the clinical research practices and productivity at UM and our collaborative partners
   c. Evaluate the impact on UM's community engagement activities
3. AIM 3: Conduct evaluation research to develop and test new methods/tools for evaluating the impact of structures like the CTSI on research philosophies, practices and outcomes

C. CHARACTERISTICS

1. Action Plan for Year 1: The action plan in Year 1 focused on making progress towards Aims 1 and 2.
   a. AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its components
      i. Meet with all components and CTSI management to assess status of each component
      ii. Develop a survey of all components to determine how specific aims had changed since grant proposal submission and to collect informed on planned activities of components
      iii. Assess whether metrics for evaluation of component required updating
      iv. Determine what resources are currently available for tracking data required for collecting evaluating components and what systems are in need of development
      v. Assess timelines for development of tracking systems that are not currently available
      vi. Develop formal and informal associations with the Evaluation Consortium and National Key Function Committee to part to ensure that we are involved in and up to date on development of national evaluation metrics
   b. AIM 2: Conduct a rigorous and on-going evaluation of the CTSI and its components
      i. Conduct a baseline survey to be completed by all components to determine activities conducted since grant proposal submission and since notice of award
2. Progress in Year 1: Activities in Year 1 have focused on organizational development of the component, and progress in Aims 1 and 2, where we have made significant progress in the development of metrics and establishment of benchmarks for the overall CTSI and the components and the overall CTSI. To this end, during the past year we have made progress in the following areas and accomplished the following goals.
   a. AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its components
      i. Organizational:
         1. Established our component "working group" team and a process for our team interaction
         2. Identified a new external consultant for the component, Dr. John H. Littlefield. Dr. Littlefield is an evaluation specialist at the University of Texas Health Science Center at San Antonio. Dr. Debra Stark our original external advisor has changed her position since the submission of our application and is no longer actively involved in CTSA activities. Dr. Stark's previous position was the evaluation specialist for the University's Academic Center for Excellence in Teaching. Dr. Littlefield served as Dr. Stark's Director.
      ii. Development of metrics:
         1. Met with all components and CTSI administration to assess the status of each component

2. Develop and conduct a baseline survey of all components and the overall CTSI to gathered information on specific aims as there were some modifications in aims since the proposal submission
3. Gathered information on the planned activities of each component for the upcoming year using the same baseline survey
4. From revised aims and planned activities, we developed a set of evaluation metrics that included both process and outcome measures for each component and for the overall CTSI

iii. Development of tracking mechanisms:
1. Met with the Biomedical Informatics Component and the leadership of our IRB to preliminarily identify databases for the metrics; collaborations are continuing
2. Met with the CTSI research navigator, P. Avissar, to discuss strategies to track the activities of the overall CTSI
3. Databases for tracking some metrics have been identified

iv. Outreach and development of component strategy and evaluation plan:
1. Presented our evaluation plan to the School of Medicine's Research Council and the CTSI Scientific Advisory Committee, as well as to our NIH program officer
2. Met with Dr. Bickman from Vanderbilt University to discuss our evaluation plans
3. Met with members of the Evaluation Component from the University of Florida to discuss evaluation strategies and learn from their experiences and expertise
4. Became active members of the CTSA Key Function Evaluation Committee; Dr. Byrne attended the annual meeting of the Consortium in Washington D.C.
5. Participate in the monthly teleconference meetings of the Committee
6. Provided input into the evaluation processes for the CTSI's CaneSearch Event

b. AIM 2: Conduct a rigorous and on-going evaluation of the CTSI and its components
i. Conducted a baseline survey with each component leader and the overall CTSI leadership to identify the progress of components and the overall CTSI since proposal submission and notification of award
ii. Tracked the initial progress of the overall CTSI and each component via the baseline survey and ad hoc data collection based on the updated metrics

3. Opportunities, challenges, strengths, weaknesses and changes
a. *Opportunities:* (i) Plans are in place for development of several technologies for collecting potential evaluation data which already exist in the university. (ii) Several components already have impressive accomplishments toward CTSI goals.
b. *Challenges:* (i) Uncertain and non-immediate timelines for completion and readiness of tracking systems for usability by the evaluation component. (ii) Uneven formation of strong relationships among component leaderships necessary to facilitate building of tracking systems to meet needs of CTSI evaluation component. (iii) Resources for coordination among the many vibrant and move parts of the CTSI to ensure adequate communication of all activities.
c. *Strengths:* (i) Critical mass of scientific, evaluation, and informatics expertise available across UM campuses. (ii) Strong support and input from National Key Function Committee infrastructure vis a vis information and past experiential knowledge. (iii) Development of working relationships with other institutional CTSI evaluation components.
d. *Weaknesses:* (i) Current lack of automation of data collection and tracking. (ii) Lack of coordination of information flow concerning activities regarding information collection at all levels of CTSI. (iii) Limited human resources for critical proactive evaluation tasks.
e. *Changes:* (i) Hiring of an additional 1.0 FTE support person for the component to interface with components and administration, and conduct computer programming tasks. (ii) Bringing on-line WebCAMP and REDCap tracking and survey systems.

D. MAJOR ACCOMPLISHMENTS

1. AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its components
a. A set of metrics that include both process and outcome measures has been developed for the overall CTSI and each component
b. Databases for specific metrics have been identified
c. Formal ties to National Key Function Committee have been established and input provided for national metrics
d. WebCAMP and REDCap identified as sources of tracking methodology
2. AIM 2: Conduct a rigorous and on-going evaluation of the CTSI and its components

a. Conducted a baseline survey with each component leader and the overall CTSI leadership to identify aims, progress and planned activities
b. Tracked initial progress of overall CTSI and each component via survey and ad hoc methodologies.

E. CTSA CONSORTIUM, ACTIVITIES AND CONTRIBUTIONS

The Component has become actively involved in the National Key Evaluation Function Committee and other institutional CTSI Evaluation components in the following ways:

1. Participation in the bimonthly KFC Evaluation teleconference meetings as well as the bimonthly Cohort Presentation calls
2. Met with members of the Evaluation Component from the University of Florida, who provided invaluable information on their experiences with evaluation strategies, logistics and approaches
3. Attended (Dr. Byrne) the last annual meeting of the Key Function Committee in October 2012. The theme of that meeting was “Developing Common Metrics for CTSA Clinical Research”, and she participated in the initial development of the national metrics, which will soon be distributed for discussion and revision
4. Attended (Dr. Byrne) the CTSA Social Network Analysis Training Workshop in March 2012, sponsored by the Evaluation KFC (prior to formal receipt of UM CTSI funding), which discussed using social networks to evaluate translational research teams and community collaborations

F. PLANS FOR COMING YEAR

1. AIM 1: Develop metrics and a system to track the activities of the overall CTSI and its components
   a. Organizational:
      i. Hire an additional technical support team member
      ii. Continue
         1. Attending the Monthly Operational Committee Meetings and the meetings of the internal and external advisory boards
         2. Involvement with involvement with the National Key Evaluation Function Committee
         3. Meet with each of the Component leaders on a regular basis (including utilizing new support team member) to discuss the progress of the component and identify any change in aims or planned activities to refine metrics as needed
         4. Meet regularly with CTSI administration to ensure that communication on all activities related to tracking and data collection are shared among evaluation and administrative components
   b. Metrics:
      i. Develop finalized metrics for longitudinal collection of data from each component and CTSI overall
   c. Tracking:
      i. Finalize identification of databases for identified metrics in collaboration with the Biomedical Informatics Component, 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 Component and the CTSI leadership
   d. Outreach and development of component strategy and evaluation plan:
      i. Meet with our External consultant, Dr. Littlefield, to gather further input on our evaluation strategies and refine as needed
      ii. Finalize evaluation strategies
2. AIM 2: Conduct a rigorous and on-going evaluation of the CTSI and its components
   a. Develop and conduct evaluation surveys with users of the CTSI component services
   b. Collect data on the identified metrics for the overall CTSI and the components using developed tracking methodologies
   c. Summarize collected data and rigorously evaluate progress of each component and overall CTSI relative to specific aims and to plans outlined in 2013 Annual Report (current report)
3. Aim 3: Conduct evaluation research to develop and test new methods/tools for evaluating the impact of structures like the CTSI on research philosophies, practices and outcomes
   a. Initiate one of our planned research projects related to recruitment and retention in CT research trials

Appendix 8

Regulatory Services Provided

Investigator/ Collaborator	Grant # and Sponsor	NIH IC	Title of Project	Core Services Provided	% Use
Maria Alcaide (UM)	CFAR	NIAID	Vaginal cleansing practices in multi-ethnic women at risk for HIV	• IRB • Monitoring plan • Manuscript help	2
Geoffrey Stone (UM)	1 R21 AI093294-01A1	NIAID	CLUSTERED RECEPTOR-SIGNALING DOMAINS AS NOVEL HIV VACCINE GENETIC ADJUVANTS	• IRB	2
Eli Gilboa (UM)	5 R21 AI087385-02	NIAID	OLIGONUCLEOTIDE APTAMER LIGANDS TO REVERSE T CELL ANERGY IN HIV-INFECTED PATIENTS	• Study population • IRB	2
Derek Dykxhoorn (UM)	5 R21 AI088601-02	NIAID	TARGETED SIRNA DELIVERY AS AN ANTI-HIV MICROBICIDE	• IRB	2
Savita Pahwa (UM)	5R01AI077501		Role of IL-21 in preservation and augmentation of CD8 T cells in HIV	• IRB	3
Savita Pahwa (UM)	5P30AI73961		Immunogenicity of HINI vaccine in HIV-1 infected populations	• IRB • Consent form • Human subjects	8
Maria Alcaide (UM)	K23HD74489-01	NICHD	Vaginal practices in HIV positive women in Zambia a bio-behavioral intervention	• Study design for safety • IRB • Monitoring plan	4
Enrique Mesri (UM)	5 R01 CA136387-02	NCI	Role of RA and reactive oxygen species in Kaposi's sarcoma viral oncogenesis	• Study design for safety • IRB	2
Suresh Pallikkuth (UM) M Sharkey (UM)	CFAR		Circulating memory CD4 T follicular helper cells are the major latent viral reservoirs in HIV infected ART treated patients	• IRB	4
Hector Bolivar (UM)	CFAR		HIV Genetic Diversity: Miami Surveillance Study	• IRB	2
Hector Bolivar (UM)	CFAR		A Study to Evaluate the Effect of Vitamin D Level on Immune Recovery of HIV-1 Infected Individuals Receiving Highly Active Antiretroviral Therapy.	• IRB	2
Jose Castro (UM) LydieTrautmann (VGTI)	NIAID Admin Supplement	NIAID	Systems Biology Approaches to Identify Adaptive Immune correlated of protection	• Rectal biopsy template • Cervical cytobrush template • IRB • Consent form • Human subjects	8
LydieTrautmann (VGTI) Jose Castro (UM)	NIAID Admin Supplement	NIAID	Systems Biology Approaches to Identify Innate Immune correlated of protection	• Rectal biopsy template • Cervical cytobrush template • Consent form and IRB • Human subjects	8
Catherine Boulanger (UM)	Abbott Laboratories		Pharmacokinetic Study of Super-boosted Lopinavir/ Ritonavir in Combination with Rifampin in HIV-1-infected Patients with TB.	• PK specimen collection safety procedures • IRB	2