a. PERSONNEL

Leaders: Arleen Brown, MD, PhD; Keith Norris, MD

Co-leaders, HSR: Martin Shapiro, MD, PhD; Ronald Andersen, PhD

Co-leaders, CERP: Daniel Castro, MD; Homero del Pino, PhD; Loretta Jones, MA

Key personnel: Bowen Chung, MD, MSPH; Eric Daar, MD; Craig Fox, PhD; Kimberly Gregory, MD, MPH; Calvin Hobel, MD; Moira Inkelas, PhD; F. Javier Iribarren MSW, PsyD; Katherine Kahn, MD; Paul Koegel, PhD; Gerald Kominski, PhD; Loren Miller, MD, MPH; Brian Mittman, PhD; Roberto Vargas, MD, MPH; Ronald Victor, MD; Michael Weisman, MD; Neil Wenger, MD; Aziza Wright, MA; David Zingmond, MD, PhD

b. STRATEGIC GOALS OF PROGRAM

Goal 1: Promote and sustain bi-directional knowledge-sharing between the community and academia.

Goal 2: Strengthen community and academic infrastructure for sustainable partnered research.

Goal 3: Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.

Goal 4: Build Health Services Research (HSR) methods into partnerships to accelerate design, production and wide adoption of evidence-based practice and behavior.

c. PROGRAM CHARACTERISTICS

Process and Progress

Drs. Brown (27% effort), Norris (9%), Shapiro (9%), Andersen (9%), Castro (10%), del Pino (10%) and Ms. Jones (15%) have oversight of CERP/HSR, which is comprised of community partners, CERP and HSR investigators. CERP staff include four community liaisons and research assistants (two are fully bilingual in English and Spanish), a program manager and, in conjunction with Biostatistics, a programmer analyst.

We emphasized projects (Table 1) and leveraging CERP resources (Table 2) to strengthen the infrastructure and capacity for partnered, high impact, multidisciplinary translational research. We received 18 proposals in response to two RFAs for community-partnered translational research and funded eight (total, $300,000; range, $30,000–$60,000), awarded in January 2013 (UCLA/University of Minnesota Cross-Institutional award) and May 2013 (Los Angeles County [LAC] Department of Health Services [DHS] Collaboration Grants).

Table 1. Program on CERP projects awarded in year 3

<table>
<thead>
<tr>
<th>Project</th>
<th>Objectives</th>
<th>Products/Progress through 10/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Disease Coordinated Care for Hispanic and Latino Seniors</td>
<td>Feasibility study of the ADC–HL with 16 Latino dementia caregivers in Minnesota. Measure changes in caregiver stress and mood, service use, dementia symptoms.</td>
<td>• IRB approval at both UCLA and University of Minnesota</td>
</tr>
<tr>
<td>(ADC-HL): Pilot Implementation</td>
<td></td>
<td>• Identified and trained participating care managers for pilot data collection</td>
</tr>
<tr>
<td>Correlation of Early Childhood Caries Risk and Obesity in Preschool</td>
<td>Implement health program, optimize the caries risk assessment tool in low-income population, and investigate the hypothesized mediators of caries and BMI change.</td>
<td>• Collected salivary samples, caries risk assessment data, and sensory phenotypes from 20 patients</td>
</tr>
<tr>
<td>Age Children Via Salivary Testing</td>
<td></td>
<td>• Perform statistical analysis on data</td>
</tr>
<tr>
<td>Health Information Exchange (HIE) Use in Small- and Medium-Sized</td>
<td>Interviews with community collaborators in L.A. (Citrus Valley Health Partners, a medium-sized primary care practices) and Minnesota (West Side CHS) to identify barriers to HIE spread.</td>
<td>• Finalized and tested two interview guides</td>
</tr>
<tr>
<td>Primary Care Practices: Understanding &amp; Eliminating the Disparity</td>
<td></td>
<td>• Key informant interviews ongoing at both sites. (25 planned)</td>
</tr>
<tr>
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<td>• Summary documents and presentation for CPOs and primary care practices</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Los Angeles County Department of Health Services Collaboration Grants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Los Angeles County Psychiatric Emergency Room Outcomes Study</td>
<td>Describe use of psychiatric emergency services (PES) at three LAC DHS hospitals, identify predictors associated with discharge vs. admitted from PES, and identify and compare longitudinal outcomes of patients.</td>
<td>• Four source datasets prepared and compiled. Harmonization of datasets ongoing.</td>
</tr>
<tr>
<td>Implementation of a Primary Care-Based Teleretinal Screening Protocol for the Los Angeles County Safety Net</td>
<td>Among patients with diabetes, assess service use, wait times and costs associated with the implementation of a primary care-based teleretinal screening.</td>
<td>• Baseline data collection nearly complete. Training protocol for teleretinal photographers in each primary care setting</td>
</tr>
</tbody>
</table>

Table 2. Projects and products/progress through 10/2013

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<tr>
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<th>Objectives</th>
<th>Products/Progress through 10/2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training protocol for teleretinal photos, 35 new patients achieved</td>
<td></td>
<td>• Trained 35 patients in teleretinal screening</td>
</tr>
<tr>
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<td>Objectives</td>
<td>Products/Progress through 10/2013</td>
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Program Director/Principal Investigator (Last, First, Middle): Dubinett, Steven M.

<table>
<thead>
<tr>
<th>Project</th>
<th>Objectives</th>
<th>Products/Progress through 10/2013</th>
</tr>
</thead>
</table>
| **Transition of asthma patients from acute care at Harbor-UCLA Medical Center (HUMC) back to community managed care organizations** | Compare asthma control, morbidity, quality of life (QOL) and health care expenditures in asthmatic children during the transition from HUMC to community HMO. | • Completed 61 telephone surveys  
• Completed 98 surveys by mail  
• Analysis of preliminary data |
| **Identifying Opportunities and Examining Evidence-Based Programs to Improve the Health of Youth in Los Angeles County** | Examine youth truancy citation data in LAC Department of Public Health (DPH) and LAC DHS; identify diversion strategies to prevent youth from entering the juvenile justice system, and develop strategies to improve health services planning for the care of youth in probation camps. | • Key informant interviews, and review of policies and protocols for process map  
• Systematic review of evidence-based diversion programs/interventions  
• Hired/trained staff to conduct interviews  
• Extramural funding (see table 2) |
| **Obesity group visits: An innovative program to deliver obesity services at DHS facilities** | Increase the obesity group visits at MLK-MACC from 10 to >30 patients per week; implement obesity groups at two other DHS facilities via videoconference (econsults); implement a database to track BMI and A1c. Establish stakeholder group for eventual PCORI proposal. | • Increased group visits to 25 patients/wk  
• Database to track weight and A1c approved by IRB  
• Infrastructure in place to start econsult obesity visits at other DHS facilities  
• Held several post-visit discussion groups and 5 stakeholder meetings |

Table 2. Funding supported by CERP infrastructure

<table>
<thead>
<tr>
<th>Funding</th>
<th>Agency</th>
<th>Period</th>
<th>Award (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving Children and Their Families (The Children's Clinic/Inkelas)</td>
<td>Everychild Foundation</td>
<td>11/13-10/16</td>
<td>$1</td>
</tr>
<tr>
<td>Long-Term Outcomes Of Community Engagement To Address Depression Outcomes Disparities (Wells/Jones)</td>
<td>PCORI</td>
<td>01/13-01/16</td>
<td>$2.06</td>
</tr>
<tr>
<td>LA Stroke Prevention/Intervention Research Program (SPIRP) Supplemental funding (Vickrey)</td>
<td>NINDS</td>
<td>09/13-08/17</td>
<td>$0.19</td>
</tr>
<tr>
<td>Magnolia Community Initiative</td>
<td>Doris Duke Charitable Foundation</td>
<td>11/13-10/16</td>
<td>$0.6</td>
</tr>
<tr>
<td>WalkABLE: Steps to a Better Quality of Life (MAK)</td>
<td>Quality and Productivity Commission of LA County</td>
<td>12/13-07/14</td>
<td>$0.2</td>
</tr>
</tbody>
</table>

d. MAJOR ACCOMPLISHMENTS BY GOAL

**Goal 1:** Promote and sustain bi-directional knowledge-sharing between the community and academia.
CERP has collected data from five symposia (830 attendees; 82% reported increase in knowledge) and three workshops (33 attendees). CERP has provided 42 consultations to researchers and community partners (70% to assist with analysis, presentations, or proposals). The consultation service has expanded to include three additional community representatives from diverse organizations and a faculty member with dissemination and implementation expertise. Over the past year, we have identified a trend toward increased trust in health research among symposium and workshop participants, increasing from 25% to 69%.

**Goal 2:** Strengthen community and academic infrastructure for sustainable partnered research.
Infrastructure/capacity building is a component of virtually all ongoing CERP projects: the Healthy Community Neighborhood Initiative (HCNI), previously the 70 Block Project (described below); the Practice-Based Research Network (PBRN) to conduct adaptive clinical trials and quality improvement at Harbor/LA-Biomed and the DHS Ambulatory Care Network; the partnered grant-writing course (Goal 3); the Healthy Aging Initiative (Goal 4); and the HSR data analysis group’s “hot spot” analysis (Goal 4).
In November 2013, the HCNI completed community asset mapping and household interviews/clinical exams (including biomarkers) with 150 African Americans and 50 Latinos. Over the next year, partnered analysis of the data will help to inform the design of a partnered risk-reduction intervention in South Los Angeles.

**Goal 3:** Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.
Nine teams participated in CERP’s 12-week community-academic partnered grant writing series (faculty came from UCLA, CDU, and Harbor/LA Biomed) to prepare either a foundation or NIH grant. Two teams received extramural funding (Children’s Clinic, Inkelas; WalkABLE, Mak); remaining teams have projects under review.
This year CERP launched a new Dissemination, Implementation and Improvement (DII) initiative to facilitate sustainable transfer of new knowledge to community and health system settings. The DII faculty helped to
establish a Master of Science degree in improvement and implementation science in the Fielding School of Public Health and will lead a regional symposium (see Goal 3 plans for coming year).

CERP co-led, with UCSF, two Deliberative Community Engagement (DCE) events (one fully bilingual) for EngageUC, a project to develop an ethical, efficient, and sustainable system for obtaining, processing, and sharing biospecimens and data. Recommendations from the DCE have been presented to UC investigators and policy makers and have been incorporated into a randomized trial of informed consent within UC.

Goal 4: Build Health Services Research (HSR) methods into partnerships to accelerate design, production and wide adoption of evidence-based practice and behavior.
The CERP/HSR team has partnered with USC, LAC DHS and LAC DPH, and local aging organizations in a county-wide program to apply and evaluate evidence-based interventions intended to promote healthy aging. The effort has attracted great interest in the county, and we are partnering with other groups seeking to improve services for the aging population in Los Angeles. The UCLA CTSI is committing resources to at least two pilot projects, possibly in partnership with the USC CTSA. We are discussing University-wide strategies for identifying additional resources to move these exciting efforts forward.

The data analysis working group assembled data on disease burden (e.g., chronic disease “hot spots” and preventable admissions) and resources in LA County to address health needs at the district level. In 2013 these data were presented in 8 meetings (113 attendees), and a full report was distributed to stakeholders (community organizations, health plans, LAC DHS, LAC DPH, and the City of Long Beach) who used our data for a conference, a successful grant proposal, and to disseminate to California state assembly staffers.

e. OPPORTUNITIES AND CHALLENGES
An ongoing challenge is to demonstrate the long-term health impact and sustainability of CERP activities. In response to External Advisory Board (EAB), we are focusing on our partnership with LAC to test innovations to improve and increase delivery of high-quality care. In addition to the recently funded projects (above), we have invited Anish Mahajan (DHS) and Tony Kuo (DPH) to join CERP leadership. Also in response to EAB, we are developing a logic model to demonstrate the relationship between CERP activities and population-level outcomes (See section g., Goal 3).

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE: None.

g. PLANS FOR COMING YEAR BY GOAL
Goal 1: Promote and sustain bi-directional knowledge-sharing between the community and academia.
Through the Consultation Service, in Year 4 we plan to design a Community Advisory Panel (CAP) curriculum for academic researchers, and an analogous curriculum for community representatives serving on CAPs. We also plan to identify a health economist who can assist the Consultation Service with requests for cost analysis.

Goal 2: Strengthen community and academic infrastructure for sustainable partnered research.
We will continue to work with LA County DHS and DPH on: 1) the practice-based research network (PBRN) to conduct adaptive clinical trials and quality improvement at Harbor/LA-Biomed and the DHS Ambulatory Care Network; 2) the DHS pilot projects; and 3) the Healthy Aging Initiative. This year we will use the logic model (Goal 3) to evaluate the strength and effectiveness of these CERP community-academic partnerships.

Goal 3: Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.
- In Year 4, we will use the logic model to review the products and impact of CERP activities; to identify features of successful projects; and to guide decisions about new and continued funding.
- We will host a regional Dissemination, Implementation and Improvement Science Symposium in March 2014 to enhance the societal impact and benefits of CTSI research, increase researchers’ and stakeholders’ competitiveness for funding, and connect individuals and organizations interested in DII.
- We will use knowledge gained from EngageUC to conduct DCE events relevant to LAC DHS and DPH.

Goal 4: Build Health Services Research (HSR) methods into partnerships to accelerate design, production and wide adoption of evidence-based practice and behavior.
With funding from the California Endowment, the health data group will release city-level data in mid-2014. As with the health district data, this information on chronic disease patterns and health service use will support proposals for funding, policy initiatives, and can be linked to other data sources, such as the Biomedical Informatics Program’s LA Data Resource (LADR).
a. Personnel

Leaders: E Kleerup, MD (20%); D Martins, MD, MS (15%); L Raffel, MD, MS (30%); I Salusky, MD (20%); C Wang, MD (27%).

Co-leaders: E Ipp, MD; M Irwin, MD; C Maida, PhD; R Mathur, MD; R Mitsuyasu, MD

Key personnel: L Burnes-Bolton, DrPH, RN; K Gregory, MD; L Jones, MA; L Smith, MD

b. Strategic Goals of Program

Goal 1: To broaden the scope and efficiency of clinical, translational and community research by implementing the CCRR without walls.

Goal 2: To promote collaborations across the CTSI partner institutions.

Goal 3: To recruit junior professionals into careers in translational clinical research.

c. Program Characteristics

c.1. Process

The CCRR has four Clinical and Translational Research Centers (CTRCs). Outpatient units are located at UCLA-Westwood, Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (LABiomed/Harbor), Charles Drew University of Medicine and Science (CDU), and Cedars-Sinai Medical Center (CSMC). Inpatient facilities are located at UCLA and LABiomed/Harbor. CTRC staff includes experienced research nurses, research bionutritionists, phlebotomists, clinical research coordinators, clinical nursing assistants, and recruitment specialists. Facilities available include sample processing labs, two metabolic kitchens, two DEXA scanners, and two sleep study facilities.

c.2. Progress

New Infrastructure Initiatives. Three projects are in the initial phase of development a) Outpatient endoscopy (expected first use UCLA, Feb. 2014), b) Electrosurgical unit for minor outpatient surgical procedures (UCLA, Jan 2014), c) Lifestyle Intervention and Food Education (LIFE) project, a community-based clinical research site (Weingart YMCA, CDU, LABiomed/Harbor, CSMC, UCLA, Apr 2014). Two initiatives are in use by their first Investigators a) Gynecologic ultrasound (UCLA, Jul 2013) b) Neuromuscular Recovery and Rehabilitation Center (UCLA Oct 2013.) Four services have been expanded to multiple protocols locally or across institutions a) Coordinator and Regulatory Services, b) Redcap for protected health information, c) Data safety and management templates, d) Walk-in phlebotomy.

Collaboration and Standardization among the Four CTRCs. A minimum data set for protocol submission information across sites has been developed. We are integrating site-specific service requests with the IRB application and implementing the ability to exchange and track information. We are in the process of posting common descriptions of facilities and services to the CTSI website to give investigators a clear idea of what is available at each site.

Seed Grants. UCLA offered two cycles of seed grants this year targeted at pilot projects and phase I studies. In the Spring 2013 round, 6 awards were made from 11 complete applications selected from 23 letters of intent. Three of the of the awards are for pilot studies of new treatments: “Does reversal of melatonin deficiency in patients with Type 2 diabetes leads to preservation of insulin secretion and glucose control,” “Repositioning Ivermectin for the Treatment of Alcohol Use Disorders,” “The effects of vitamin D3 versus 25OHD3 supplementation on serum vitamin D metabolites and markers of mineral metabolism and immune function.” Half of the awards were to mentored new investigators. The fall UCLA cycle is under review and additional CTRC sties will join the spring 2014 cycle.

Operationalizing Clinical Research. The CTRC’s continue to provide support for our many clinical and translational investigators. In 2013, 233 (43 CSMC, 17 CDU, 109 LABiomed/Harbor, 64 UCLA) existing research projects continued and 193 (13, 9, 45, 126) new protocols were initiated. For the first 11 months of the reporting period, an average of 754.0 (217.2, 42.7, 246.3, 247.8) outpatient visits/month were performed (annualized 9,048 per year). Control chart analysis (Fig. 1) demonstrates the stability of the overall usage (-1.9%), but an increase at CSMC and UCLA (noted by Jul), a likely increase at CDU and a decrease at
LABymed/Harbor (May). As planned, there has been a reduction (-13.3% compared to year 1-2) in inpatient overnight stays. An average of 47.9 (28.9 LABymed/ Harbor, 17.9 UCLA) inpatient days/month were performed (annualized 574.9 per year). Control chart analysis demonstrates the usage is erratic and likely driven by individual projects (e.g., drug abuse studies with long washout stays).

**Cofunding.** The progressive increase in the portion of costs paid by non-industry grants is advancing toward our 50% target. Our concern is that this charge-back mechanism does not unacceptably impact utilization and young investigators. A five-year grant at UCLA funded in 2013 pays 31% of the charges, but 11% if the PI is a young investigator.

**Educational Initiatives.** We have specifically recognized the educational role of the CTRCs for investigators, coordinators and potential future investigators.

**d. MAJOR ACCOMPLISHMENTS**

**Goal 1: To implement the CCRR without walls.** The restructuring of the CTRCs succeeded in shifting the focus to outpatient research while still offering support to investigators who require inpatient services. Mobile nursing to non-CTRC locations in the hospitals and clinic sites has offset the 13.3% reduction in inpatient stays. Beginning in 2014, the Weingart YMCA will provide a new venue in specific minority communities for recruitment and clinical research activities. A survey has been deployed (Dec 2013) to assess the needs of current CTRC users (N=354) and non-users (N=362).

**Goal 2: To promote collaborations across the CTSI partner institutions.** Regular communication and monthly videoconferences among the CCRR leadership and staff have improved coordination. As part of our standardization efforts, in January 2014 we will list each site’s facilities and services on the CTSI website. After that, we plan to standardize cross-institutional service requests and tracking of services performed. We have also begun extending this to the pricing model CTRC and CERP supported the well-attended, Nov. 2013 Obesity Symposium at LABymed, which was organized to spur local and national research collaborations.

**Goal 3: To recruit junior professionals into careers in translational clinical research.** The CCRR leadership regularly provides one-on-one guidance on operationalizing translational clinical research to junior faculty. The seed grant program has provided services and CTRC resources for young and new translational investigators. We actively participate in CTSI education and training activities, including the Training Program in Translational Science the Clinical Scholars Program the Pathway on Clinical and Translational Medicine the Long Beach Polytechnic High School program, and educational workshops.
e. OPPORTUNITIES AND CHALLENGES

In the past year the Clinical and Translational Research Center (CTRC) has 1) increased efficiency in CTRC utilization; 2) implemented cost sharing for services; 3) made great progress in developing synergy among the CTRC units; 4) adjusted to budget cuts without reduction in service; and 5) developed hands-on training programs for junior investigators. The External Advisory Board identified two issues of concern for CCRR:

“There is a major opportunity to engage the health system in expansion of CTRC-supported pilot studies to take advantage of resources available from all partner institutions and LA region, particularly for implementation science projects.”

We agree that this is an extremely important issue and is one that extends beyond the functions of the CTRC program, involving many different aspects of the CTSI including health services research, comparative effectiveness research, patient-centered outcome research and community-based and partnered research. In 2013-2014 the CTRC will be supporting several pilot projects aimed at combating adult and childhood obesity including: J. Yee (LA BioMed), funded by Unihealth Foundation; and T. Friedman (CDU), funded by CTSI/LAC DHS. CDU and Weingart YMCA in South Los Angeles have created a new academic-community partnership to establish a lifestyle intervention and food education center for the YMCA members and its surrounding urban underserved population. The project is led by David Martins, MD (CDU) with major roles being played by the bionutritionists from the three other CTRC sites. The initial step is creation of dietary education programs tailored to the communities (African American and Hispanic). This partnership will serve both as a community hub for translational research and a resource for the community. It will allow pilot studies to compare the cost and effectiveness of intervention delivered by trained community health workers at the YMCA versus primary care clinic health professionals. We are also exploring the possibility of engaging young chefs who are currently enrolled in the Culinary Program at LA Trade-Technical College to hold cooking demonstrations introducing the use of a wide range of lower cost, fresh produce in the context of traditional ethnic cuisines.

“It would be nice to see more compelling metrics of success. Are you used because you provide subsidies, because you provide services not available elsewhere, or because you do things better? What large clinical research groups are NOT using your services and what is their rationale?”

To address these issues, a survey was launched in December 2013 to determine CTRC services and resources of importance to current CTRC investigators and those not presently using the CTRC. Survey results will guide prioritization of CTRC services and aid development of new services.

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE

While we acknowledge the critical importance of transitioning to a cost-sharing model, we recognize that cost sharing may be very difficult for some investigators, particularly young investigators without alternative resources. Thus, in addition to applying different cost-sharing expectations to junior investigators, we are exploring other means of supporting pilot research activities (such as the new Seed Grant RFA).

g. PLANS FOR COMING YEAR BY GOAL

Goal 1: To implement the CCRR without walls. We will implement the Weingart YMCA LIFE Center and advertise its availability for community outreach, recruiting, and testing the feasibility of performing clinical research in a non-traditional hospital/clinic setting. We will use the investigator survey to identify unmet needs of research teams and implement services that may benefit multiple research programs, including those noted in new infrastructure initiatives above. We will better document services performed outside the CTRCs.

Goal 2: To promote collaborations across the CTSI partner institutions. We will continue to offer our support for helping investigators identify collaborators across the partner institutions. We will continue to standardize our processes across sites and expand our new initiatives to multiple sites.

Goal 3: To recruit junior professionals into careers in translational clinical research. Through interactions with the CTSI-ED, the CCRR will continue to identify young clinical investigators and assist them in developing and funding (e.g., seed grants) research projects, providing pre- and post-award assistance in protocol development, budget development, and establishment of inter-institutional collaborations. We will also continue efforts to identify medical students interested in translational research and encourage their participation in the Pathway on Clinical and Translational Medicine.
a. PERSONNEL

Leaders: Robert M. Elashoff, PhD; Steven Piantadosi, MD, PhD; David Elashoff, PhD; Andre Rogatko, PhD

Co-leaders: Teresa Seeman, PhD; Magda Shaheen, MD, PhD; Youngju Pak, PhD; Roger Lewis, MD, PhD

Key personnel: Thomas Belin, PhD; Catherine Crespi, PhD; David Gjertson, PhD; Xiuning Guo, PhD; Steve Hovarth, PhD, ScD; Gang Li, PhD; Li-Jung Liang PhD, Chi-Hong Tseng, PhD, Thomas Graeber, PhD, Ning Li, PhD, Peter Liu, MD; Martin Lee PhD, Mourad Tighiouart, PhD; X. Wang, PhD; H. Wang, MD, MPH

b. STRATEGIC GOALS OF PROGRAM

Goal 1: Provide coordinated, one-stop access to biostatistics, computational biology and clinical data management (CDM) consulting services.

Goal 2: Develop novel statistical applications and methodologies to address the complexities of biological data and unique requirements of community-based research.

Goal 3: Provide biostatistical education and training.

c. PROGRAM CHARACTERISTICS

c.1. Process

Leadership: Biostatistics program leaders and members are situated at our four partner institutions: UCLA-Westwood, Cedars-Sinai Medical Center, Los Angeles Biomedical Institute at Harbor-UCLA Medical Center, and Charles Drew University of Medicine and Science (CDU). Our leaders (R. Elashoff, 20% effort; S. Piantadosi, 5% effort; D. Elashoff, 15% effort; A. Rogatko, 25% effort) meet monthly and frequently communicate via email and telephone. In year 3, the leadership focused on activities of budgeted staff, activity logs for those receiving % salary support, and staff availability and expertise. Of importance was resource allocation to ensure appropriate and timely biostatistical collaboration was available for service requests and projects. Dr. Peter Christensen retired from LA Biomed and was replace by Dr. Youngju Pak who has taken over responsibility for leading the CTSI Biostatistics program at that institution.

Staffing: In year 3 the biostatistics program faculty were supported by five master’s degree statisticians (Tristan Grogan, Sitaram Vangala, Lewei Duan, Francine Anene [UCLA-Westwood] and James Mirocha [CSMC]). Mr. Grogan, Ms. Anene and Mr. Mirocha provide data analysis, data management and manuscript preparation assistance. Mr. Vangala takes on biostatistical consulting responsibilities for projects arising in the Community Engagement in Research Program (CERP) under the direction of Drs. Liang and Elashoff. Additionally, to provide collaborative support for high throughput molecular data analysis Dr. Thomas Graeber (10%), Dr. Xiaoyan Wang (20%) and Dr. Steve Horvath (5%) oversee the effort of Ms. Duan (50%) and graduate students in Dr. Graeber’s lab. The program was also supported by two part-time administrative staff and three PhD statisticians at 10–40% effort. Biostatistics Program has contracted with the UCLA-Westwood Department of Pediatrics to take on statistical teaching and consulting activities within the department in exchange for support of 50% of assistant professor Dr. Ning Li’s appointment in the SOM Dept. of Biomathematics. This allows the program to provide an enhanced level of service to collaborations. Dr. Lee was added as CTSI faculty at CDU to provide additional biostatistical consulting service.

Service Prioritization: The biostatistics program provides services based on the following criteria: (1) graduate students, medical students, fellows, and assistant professors without current funding to obtain sufficient support to generate preliminary data for career development and/or research project grant submissions; (2) although we do not put a limit on CTSI support, we require recharge to the CTSI when investigator funds exist; and (3) CTSI support for investigators from other CTSAs is negotiated among the CTSAs involved.

Effort Tracking: In collaboration with the biomedical informatics program (BIP) and in response to an EAB critique we started utilizing the team science workflow management system (TSS) that provides a common platform and database for logging effort on projects and tracking progress.
c.2. Progress

Statistical Consulting: Exclusive of administration and special courses, the total statistical consulting hours with investigators at the four institutions was 8442.25 for the period Jan. 1, 2013 to Nov. 1, 2013. This was broken down as follows: 4252.5 hours for data analysis; 1895.25 hours for study design and analytic protocol development; 1316 for short consultations and manuscript advice/preparation, and 842 hours in data management. We have collaborated on 899 projects. The overall level of consulting was lower than year 2 due to the reduction in available consulting hours; one of our statisticians was on leave and then resigned. Our collaborations resulted in the publication of 50 manuscripts in this grant period. These include 6 statistical methodology publications. We assisted 461 unique investigators. The consulting hours were approximately equally split between trainees, junior faculty, and senior faculty. Additionally, the program successfully implemented a weekly drop-in statistical consulting service at UCLA that had 71 attendees in this grant period. We provide biostatistics/computational biology consulting services for those who receive CTT genomics vouchers. This ensures that genomics data produced by these vouchers be analyzed appropriately. We initiated a data management design consulting service to assist investigators in designing and developing REDCap databases.

Educational Activities: Biostatistics program faculty lectured on introductory statistics at all four partner institutions and assisted with multiple grant writing workshops. We gave statistics lectures in the CTSI TL1 summer program. Biostatistics program faculty continued to teach courses in the Master's in Clinical Research (MSCR) program including courses on clinical trials (4 courses), regression analysis, longitudinal and multivariate data analysis, high throughput microarray and sequencing data analysis, scientific writing, and methodology for observational studies. All courses are video conferenced to the partner institutions and the videos and course materials are available via the Moodle implementation on the main CTSI website.

Committee Service: Biostatistics program faculty participate in the program area leaders meetings, the Education Core CREST committee, and the CTRC scientific advisory committees (SAC). For the SAC committees we provide statistical reviews for CTRC studies across the institutions.

Evaluation: Via an online service request system on the CTSI website, the BIP program solicited evaluations for our consulting service. The first 48 surveys demonstrated a high degree of satisfaction with the quality and timeliness of service (90% of respondents reporting extremely or very satisfied on both metrics) and 95% responding that they are extremely likely (81%) or very likely (13%) to recommend the service.

d. MAJOR ACCOMPLISHMENTS BY GOAL

Goal 1: Provide coordinated, one-stop access to biostatistics, computational biology and clinical data management (CDM) consulting services.

Key outcomes of the program’s collaborative research include:

- Drs. R. Elashoff and Ron Victor at CSMC developed a novel community-based clinical trial studying the delivery of hypertension therapy via barbershops in the African American community. This randomized longitudinal cluster randomized trial has recently been funded by NIH. This project required extensive collaboration in the development of a novel study design and a novel analytic protocol. The proposal, which requested $8.5 million over five years, received a fundable, 5-percentile score. It goes to council in February 2014 with a start date of April 2014.

- Drs. D. Elashoff and X. Wang collaborated with Dr. David Wong to develop project to discover and validate extracellular RNA markers for gastric cancer detection using RNA sequencing technologies. This project received $5 million over five years through the UH2/UH3 extracellular communication program from NCATS. This project required a rigorous experimental design and the design of a data analytic pipeline to handle the large amounts of RNA sequencing data to be generated.

- Drs. Graeber and D. Elashoff collaborated with Dr. R. Modlin on a gene expression study of the effects of type I interferon on human anti-mycobacterial responses that was published in Science.

Goal 2: Develop novel statistical applications and methodologies to address the complexities of biological data and unique requirements of community-based research.
Dr. Horvath published three manuscripts relating to analysis of high throughput genomic data. One paper (Song, Langfelder and Horvath; PMC3645958) provides a comprehensive evaluation of random generalized linear models (GLM) as a means for developing highly accurate and interpretable ensemble predictors in the context of genomic datasets. Ensemble predictors produce large numbers of models utilizing combinations of multiple models developed using a single dataset. This paper describes a novel bootstrap aggregated (bagged) GLM predictor that incorporates several elements of randomness and instability (random subspace method, optional interaction terms, forward variable selection) that often outperforms a host of alternative prediction methods including random forests and penalized regression models (ridge regression, elastic net, lasso). This random generalized linear model (RGLM) predictor provides variable importance measures that can be used to define a "thinned" ensemble predictor (involving few features) that retains predictive accuracy.

Drs. Ning Li, Gang Li and Robert Elashoff published a manuscript (Li et al.; PMC 3855104) examining fixed and random effects selection for longitudinal binary outcomes in the presence of nonignorable dropouts. This paper explores a Bayesian approach to selection of variables that represent fixed and random effects in modeling of longitudinal binary outcomes with missing data caused by dropouts. This manuscript demonstrates via analytic results for a simple example that nonignorable missing data lead to biased parameter estimates. This bias results in selection of wrong effects asymptotically, which we can confirm via simulations for more complex settings. By jointly modeling the longitudinal binary data with the dropout process that possibly leads to nonignorable missing data, we are able to correct the bias in estimation and selection. Mixture priors with a point mass at zero are used to facilitate variable selection. This methodology is important for the analysis of trial data in scenarios with dropouts that are correlated with the outcome as often occurs in community clinical trials.

e. OPPORTUNITIES AND CHALLENGES

Based on the recommendations of the EAB we have changed the name of the program to the Biostatistics program from the Biostatistics and Computational Biology program. Based on EAB recommendations we plan to collaborate with the BIP program to develop additional infrastructure for improving REDCap support by building common vocabularies as well as linkages between REDCap and other campus data sources such as xDR. An additional EAB recommendation was to consider more sustainable financial models. In response we plan to pursue co-funding relationships with additional departments and divisions and will widen the scope of our existing recharge mechanisms to recover costs when projects’ needs exceed the maximum free support levels. We will roll out biostatistics vouchers through the CTT program in year 4.

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE. None

g. PLANS FOR COMING YEAR BY GOAL

Goal 1: Provide coordinated, one-stop access to biostatistics, computational biology and clinical data management (CDM) consulting services.

We plan to continue to provide consulting for study design, data analysis, computational biology, REDCap databases and data management. We plan a new staff-level hire to replace the full-time staff member that resigned this year. Through the expanded use of recharge and co-funding we plan to add three staff statisticians to provide increased data analytic support.

Goal 2: Develop novel statistical applications and methodologies to address the complexities of biological data and unique requirements of community-based research.

We plan to continue the development of statistical methods for complex biological data with an emphasis on ensemble methods and network analysis. Additional research work will be conducted on the handling of non-ignorable missing data generated in clinical trials with specific application to studies conducted in the community.

Goal 3: Provide biostatistical education and training.

Develop a new course for the MSCR program on the design and analysis of longitudinal and community trials. In spring 2014 we plan to introduce a new class focusing on practical training in research methodology with topics including data collection, databases, data management, monitoring, auditing, regulatory requirements and budgeting.
a. PERSONNEL

Leaders: Stanley G. Korenman, MD
Co-leaders: Stuart Finder, PhD; Stewart Laidlaw, PhD; Eifaang Li, DVM, MPH; Catherine Mao, MD; Junko Nishitani, PhD; Leslie Raffel, M.D. Laurie Shaker-Irwin, Ph.D, MA
Key personnel: Alison Orkin

b. STRATEGIC GOALS OF PROGRAM

Goal 1: Harmonize regulatory mechanisms throughout the UCLA CTSI to promote easy access to translational research opportunities for scientists, staff, community members and study subjects.
Goal 2: Create a UCLA CTSI-wide "one-stop shop" for approval and oversight of CTSI-supported science.
Goal 3: Develop a Research Ethics Consortium for CTSI investigators and participants to enhance ethical sensitivity, understanding of regulations and good clinical practices, and mentoring and learning.

c. PROGRAM CHARACTERISTICS

c.1. Process

Dr. Korenman (40% effort) directs all aspects of the program and leads the ethics efforts at Westwood. Dr. Laidlaw (5%) leads LABiomed IRB harmonization and compliance efforts. Dr. Finder (5%) leads the ethics program and with Dr. Raffel (5%) manages post-approval oversight and conducts ethics consultations at Cedars-Sinai; Dr. Li (5%) leads the Institutional Review Board (IRB) harmonization work; and Drs. Mao (30%) and Shaker-Irwin (10%) direct the Post-approval Research Oversight (PARO) program, which includes Research Subject Advocacy (RSA), but is primarily involved with the CTRC Program; Ms. Orkin has 5% effort at no pay. Dr. Nishitani (5%) works on IRB harmonization and research compliance at CDU. Leaders work collaboratively in groups but are physically located at and supported by their home institutions.

c.2. Progress

In the past year, IRB harmonization work focused on , integrating reporting, and enhancing the reliance mechanism. The program started working with key committees whose approval is required before a multi-institutional study is activated. These committees include Privacy, Biosafety, Conflicts of Interest, Radiation Safety, Radioactive Drugs, and Stem Cell Review; standardizing requirements and timing with these committees is critical for the CTSI reliance mechanism to work and to avoid unanticipated delays. CTRC approval may have also delayed study activation. The CTRC approval process has just been greatly improved (see below). Coverage analysis, a very important function for clinical trials that has led to major research delays of clinical trial initiation, is now being aggressively addressed (see below). Drs. Finder and Korenman are involved in the development of a collaborative ethics consult service to support the needs of CTSAs with and without in-house ethics programs, to non-CTSA institutions and to commercial entities.

d. MAJOR ACCOMPLISHMENTS BY GOAL

Goal 1: Harmonization (pre-clinical) Regulatory Program initiated development of an animal research harmonization MOU among CTSI partner institutions. Areas identified as needing thoughtful attention included animal transfer between facilities with the risks of contamination, training and certification of employees to work at one another’s facilities, and liability for injury and damages. Harmonization (clinical). In the past 9 months 14 new Reliance-Review IRB studies have been activated, three of which involve three CTSI partner institutions. Our goal for the full year was 18; at the current rate we project 19. IRB Metrics. Table 2 below presents IRB turnaround times for the nine months ending Sept. 30. (Numbers may not add due to rounding.) The times are not substantially different from year 2. The fact that median values were consistently lower than the means suggests that a few problem proposals disproportionately contributed to average review times. We
are organizing a more detailed set of metrics to begin with the new year and to be reported frequently to distinguish investigator versus IRB-associated delays in completion.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Full Committee Review</th>
<th>Expedited Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cedars-Sinai Medical Center</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total # of New Studies Approved</td>
<td>105</td>
<td>154</td>
</tr>
<tr>
<td>Days from Submission to 1st IRB Action</td>
<td>58</td>
<td>52</td>
</tr>
<tr>
<td>Days from 1st IRB Action to Approval</td>
<td>18</td>
<td>11</td>
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<tr>
<td>Days from Submission to Final Approval</td>
<td>76</td>
<td>69</td>
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<tr>
<td>Days from Submission to 1st IRB Action</td>
<td>10.5</td>
<td>10.5</td>
</tr>
<tr>
<td>Days from 1st IRB Action to Approval</td>
<td>57.5</td>
<td>57.5</td>
</tr>
<tr>
<td>Days from Submission to Final Approval</td>
<td>68</td>
<td>68</td>
</tr>
<tr>
<td>Days from Submission to 1st IRB Action</td>
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</tr>
<tr>
<td>Days from Submission to Final Approval</td>
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<td>44.5</td>
</tr>
<tr>
<td>Days from Submission to Final Approval</td>
<td>74.4</td>
<td>69.5</td>
</tr>
<tr>
<td>Days from Submission to 1st IRB Action</td>
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<td>25</td>
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<tr>
<td>Days from 1st IRB Action to Approval</td>
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</tr>
<tr>
<td>Days from Submission to Final Approval</td>
<td>74.4</td>
<td>69.5</td>
</tr>
</tbody>
</table>

Goal 2: Create a UCLA CTSI-wide “one-stop shop” for approval and oversight of CTSI-supported science. Since January 2013, Dr. Shaker-Irwin has re-engineered the Scientific Advisory Committee process at the Westwood site, revised the application, and assisted in updating the website. Applications are examined promptly and only those few that have not had serious prior scientific review are evaluated for scientific quality by the Scientific Advisory Board. All protocols are now promptly vetted operationally. 128 studies completed the CTRC process this year.

The Post-approval Research Oversight (PARO) group, which includes the RSA/DSM advisor from each CTRC and some IRB staff, continues to proceed toward harmonization. They are first aligning and improving the front-end process of helping the investigators develop appropriate study specific DSMPs. They have created and approved downloadable DSMP guidelines to help investigators select and prepare the correct template from four standardized options for their DSMP. The guidelines and DSMP templates have been incorporated into the IRB application at the LA BioMed site. The CTRCs have agreed to incorporate the template into applications for protocols utilizing reliance-review to perform studies at more than one CTSI site.

PARO continues to examine the DSM process at each center in the effort to develop uniform language and processes throughout the CTSI with the goal of relying on the primary partner for the review for protocols that are performed at multiple sites. Presentations from one site at PARO meeting of a protocol and the DSMP review process for that protocol has built confidence and made it possible to consider further consolidation.

Along similar lines, PARO plans to include reciprocal review of a few protocols by the RSA at the different institutes for quality assurance.

Goal 3: Develop a Research Ethics Consortium for CTSI investigators and participants to enhance ethical sensitivity, understanding of regulations and good clinical practices, and mentoring and learning. Drs. Korenman and Finder provide investigators and institutional administrators with consultations on
Dr. Korenman conducted six ethical research consultations and Dr. Finder conducted 12. There has been one consultation at LABiomed and none at CDU. Dr. Korenman continued to give the course on the Responsible Conduct of Research Involving Humans at UCLA and Drs. Finder and Laidlaw contributed to similar programs at their institutions.

e. OPPORTUNITIES AND CHALLENGES
The Regulatory Program has been active in trying to reduce the time involved in regulatory review by IRBs, a major criticism of the External Advisory Board. We have been meeting with representatives of the other UCs in BRAID to determine whether one or another school is doing the job significantly more effectively and that does not seem to be the case. Our figures seem near the national averages. For the coming year, we will use more detailed metrics to determine the process delays and attack them. A major challenge of the reliance-review IRB is a lack of software for managing the studies operating under the reliance mechanism. Reports and registering protocol amendments, adverse events, protocol variations and violations are time and personnel-consuming. We intend to lobby for NCATS to support purchase or development of a Translational Research Reliance software system to systematically manage approved reliance protocols and assist with the application and approval process. The External Advisory Board challenged Regulatory to identify all the steps involved in proposing, submitting and executing a research study and trying to identify and attack the delays in subject recruitment derived therefrom. UCLA has recruited a Medical Director of Clinical Research and provided staff positions charged to markedly improve the process of clinical research in multiple ways; by deploying a Clinical Research Management System and linking research to Care Connect, our electronic medical record; by applying much more effort to coverage analysis; and by developing a single integrated electronic protocol submission for all clinical research studies to include materials necessary for submission to the appropriate reviewing bodies including the CTRC. This extensive and expensive commitment of the University is designed to standardize and optimize clinical research. It will be associated with intensive evaluation of process and progress. It is an example of the CTSI’s role in transforming the University’s approach to translational research.

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE.
UCLA IRB Director Sharon Friend retired. Her successor, Alison Orkin, joined the program. Brian Kan longer participates in program leadership.

h. PLANS FOR COMING YEAR BY GOAL

Goal 1: Harmonization. Increase reliance-review studies by 50% or more. Work with Evaluation and the Biomedical Informatics Program to identify roadblocks in the IRB process and propose solutions. We will complete an analysis of the IRB process at UCLA-Westwood by May 2014 and propose potential solutions to CTSI and campus leadership by September 2014. We will then take what we have learned to our partner institutions. In 2013 we started collecting detailed metrics of full review proposals to determine where the processing delays occur and attack them directly. Our goal is to reduce IRB throughput time by at least 10 days at Cedars, Westwood and Charles Drew University over the next 12 months. Complete the animal research harmonization process. The outcome will be more exchanges of animals and staff and more research done in different partner’s facilities as measured by asking the IACUCs to report the metric.

Goal 2: Develop pre- and post-approval regulatory support services creation of a UCLA CTSI-wide “one-stop shop” for approval and oversight of CTSI-supported science. Our goals are to align and improve language and processes across sites, reach agreement to integrate the uniform language and processes into PARO and use reciprocity in oversight at least in 20% of proposals over the next 12 months. Complete the animal research harmonization process. The outcome will be more exchanges of animals and staff and more research done in different partner’s facilities as measured by asking the IACUCs to report the metric.

Goal 3: Develop a Research Ethics Consortium for CTSI investigators and participants to enhance ethical sensitivity, understanding of regulations and good clinical practices, and mentoring and learning. Our plans are to continue to provide Ethics consults and work with the national ethics group. We anticipate the same number of local consultations next year.
a. PERSONNEL
Leader: Leonard H. Rome, PhD
Co-Leaders: Richard Baker, MD; Timothy Deming, PhD; David I. Meyer, PhD; Leon Fine, MD; Judith Gasson, PhD; Owen Witte, MD; Irvin Chen, MD, PhD; Michael Irwin, MD; Paul S. Weiss, PhD; Dorothy Wiley, PhD, RN; and Hong Wu, MD, PhD

b. STRATEGIC GOALS OF PROGRAM
Goal 1: Advance transformative collaborative translational research though broad-ranging funding mechanisms.
Goal 2: Develop novel clinical and translational technologies and methodologies.
Goal 3: Attract and enable the next generation of faculty to establish careers in team-based clinical-translational research.
Goal 4: Using a multidimensional recruitment strategy, recruit at least 30 new CTSI translational research faculty over the next five years to ensure that the UCLA CTSI fulfills its academic research and teaching mission.

c. PROGRAM CHARACTERISTICS

c.1. Process
This program is managed by Dr. Leonard Rome (20% effort), Professor of Biological Chemistry, in the David Geffen School of Medicine (DGSOM) at UCLA with regular input from CTSI Director, Dr. Dubinett. Dr. Rome has regular meetings with the Program Co-Leaders: Dr. Richard Baker (5%) from Charles Drew University of Medicine and Science (CDU); Dr. David Meyer (5%) from Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (Harbor); and Dr. Leon Fine (2.5%) from Cedars-Sinai Medical Center (Cedars).

Dion Baybridge, Director of Research, works with Dr. Rome to support administration of this program and also supports the finances in close partnership with Matthew McPeck, the CTSI Financial Officer. Mr. Baybridge and his office have provided 20% effort at zero salary as this time is given as institutional contribution from the DGSOM. Web support to the program comes from the Computer Technologies Research Laboratory (CTRL), a Web programming core facility that reports to Dr. Rome. A portion of the cost of program development of the Pilot Program is also provided by the DGSOM as part of the institutional contribution to the CTSI.

c.2. Progress
The pilot program has a broad range of support mechanisms that have been implemented over the first three years of the program. All of the grant programs provide the structure and resources to increase overall efficiency of the program, improve access for junior investigators to mentors and resources to help them succeed, and to expand the process to include CTSI research and community partners.

We conferred 20 CTSI Junior Faculty Mentored Awards, 25 CTSI Seed Grants, supported three UCLA/CDU Resource Centers for Minority Aging/Center for Health Improvement for Minority Elders (RCMAR/CHIME) Scholar Awards and three Los Angeles County Department of Mental Health Fellowships with USC. The CTSI Junior Faculty Mentored Award Program is a seed grant program that provides mentored research in all areas of investigation to junior faculty at the Assistant Professor level.

The Pilot Program leadership has established a grants review oversight committee to analyze, rank and examine the grant reviews and make final funding decisions. The Research Education, Training and Career Development Program and Center for Translational Technologies also utilize this online tool to administer applications for their KL2 and voucher programs, respectively. Grant applications are submitted online though the CTSI website using an RFP tool developed in year one.
The **Team Science Awards** supports multidisciplinary team-based research. We successfully partnered with centers, institutes, departments and other entities to co-fund seven Team Science Awards this past year which address neuroscience, cancer, AIDS, and heart disease. We are partnering with the UCLA Children’s Discovery and Innovation Institute (CDI) to co-sponsor Team Science Awards in Children’s Health. Proposals are currently being reviewed and will be in year 4. Additionally, we are developing new partnerships to raise institutional resources in Muscular Dystrophy and Neurodegeneration for future Team Science Awards in these important areas. We will be partnering with Los Angeles County Department of Health Services and the Department of Public Health, the UCLA Clinical and Translational Science Institute (CTSI) and the Southern California Clinical and Translational Science Institute (SC CTSI) to establish the 2014 UCLA and USC CTSI Healthy Aging Team Science Award to advance aging research and to promote healthy aging for older adults throughout Los Angeles (see CERP report for details).

We developed the **Catalyst Grants** to create collaborative opportunities between basic and clinical faculty and community partners and to promote productive interdisciplinary collaborations to sponsor numerous seminars, retreats, programs, networks and think tanks. This past year 19 awards totaling $591,850 ($82,538 from CTSI support; $509,312 from institutional support) supported such activities as the UCLA/USC/USCF Craniofacial Biology and Translational Medicine Retreat, the Business of Science Center (BSC)-CTSI Medical Innovation Challenge (Inventathon), the UCLA-USC-Caltech Symposium entitled "Nanotechnology Innovations in Cancer, Regenerative Medicine and Infectious Diseases" and the Conference with Harbor UCLA in Identifying Strategies to Optimally Address the Obesity Epidemic in Los Angeles County.

CTSI Seminar Series is partially sponsored by a Catalyst Award. The seminar is dedicated to bringing leaders in science, medicine, industry, policy, communication and creative thinking to the UCLA community via a series of weekly presentations that are webcast to our partner sites. The weekly CTSI Seminar Series features top scientists, physicians, industry leaders, authors, creative thinkers, and community leaders. With an average audience of 200, it is the most prestigious and popular lecture series on the UCLA campus. In addition, the CTSI Seminar Series is now part of an outreach program for high schools within the LA Unified School District. The purpose of the **Novel Translational Technologies and Methodologies** (NTTMs) Grants is to foster the development of any research tool, technique, or resource with the potential of bridging critical gaps in the conduct of translational biomedical science. We awarded one **Prototype Grant** for $40,000 this past year to Thoracic Surgery to support technology development of a Video-guided Chest Tube Insertion System (“VisiTube”). VisiTube combines visual monitoring with steerability and a “Direct-Inject” anesthetic port, while maximizing patient safety and comfort.

d. MAJOR ACCOMPLISHMENTS BY GOAL

**Goal 1: Advance transformative collaborative translational research through broad-ranging funding mechanisms.**

The Pilot Program has funded, co-funded or supported through institutional matching 73 pilot grants this year. These awards leveraged $1.6 million in direct CTSI and $2.2 million in institutional matching support. Of the total, we partnered with UCLA centers and institutes to fund seven Team Science awards with $450,000 in CTSI support and $750,000 in institutional support. We have seen a combined return of more than $34 million on more than 240 pilot awards. In addition, an $8.5-million, R01 proposal to study a hypertension intervention in African American men received a fundable score in the 5-percetile range in October 2013. Earliest start date is April 2014.

**Goal 2: Develop novel clinical and translational technologies and methodologies.**

In year 3, we have partnered with the School of Medicine for the UC Center for Accelerated Innovation (CAI) which will devote substantial resources to our CTSI researchers through infrastructure and Technology Development Grants. We anticipate some of these grants will support development of new tools (see Highlights section for details about the CAI).

**Goal 3: Attract and enable the next generation of faculty to establish careers in team-based clinical-translational research.**
We funded 23 CTSI Junior Faculty Mentored Awards in the past year. These awards were made in partnership with UCLA Centers, Institutes and Departments to leverage our existing resources which provided co-funding of $708,558 in addition to the $639,636 provided by CTSI for these awards. Utilizing pilot award funds and through dynamic partnerships with departments and institutes we have successfully expanded the KL2 Program to include 6 additional junior faculty positions.

**Goal 4: Using a multidimensional recruitment strategy, recruit at least 30 new CTSI translational research faculty over the next five years to ensure that the UCLA CTSI fulfills its academic research and teaching mission.**

In addition to the aggressive interdisciplinary recruitment efforts at UCLA, each partner institution applied similar recruitment strategies to successfully recruit new high-impact CTSI clinical translational research faculty since our last progress report.

e. **OPPORTUNITIES AND CHALLENGES**

Our External Advisory Board (EAB) noted the following for opportunities for improvement: define criteria for CTSI acknowledgement and assessment of return. In response to this recommendation we are working to educate our faculty via announcements, seminars, and administrative communications on how to properly acknowledge the CTSI. We require faculty to agree to include proper acknowledgements on all published findings resulting from CTSI pilot awards before they can accept our awards. We are standardizing our reporting systems to track return for pilot awards that would not have been possible without the support of the CTSI.

f. **MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE**

As recommended by our EAB, we have increased the frequency of our Catalyst Grant program to every four months. Additionally, letters of intent to apply for a CTSI Team Science Awards can now be submitted at any time, thus allowing departments to submit requests once required matching funds are acquired.

g. **PLANS FOR COMING YEAR BY GOAL**

**Goal 1: Advance transformative collaborative translational research though broad-ranging funding mechanisms.**

We are partnering with the Los Angeles County Department of Health Services (LAC DHS) to continue joint funding of a pilot award program focused on health system improvement and efficiencies in health care delivery (see CERP report).. We have also established a collaboration with the USC CTSA to establish a funding mechanism in support of the Healthy Aging Initiative.

**Goal 2: Develop novel clinical and translational technologies and methodologies.**

CTSI is working closely with Dr. Michael Palazzolo in the Center for Accelerated Innovation (CAI) to identify novel translational technologies that would benefit from Consultation Awards. The CTSI Pilot Program will partner with the CAI and awardee departments to fund Consultation Awards that will support in-vivio proof of principle, hypothesis testing, IP assessment, target product profile discussion, regulatory assessment, and further technology development planning.

**Goal 3: Attract and enable the next generation of faculty to establish careers in team-based clinical-translational research though the Junior Faculty Mentored Awards**

As stated above we have funded 23 CTSI Junior Faculty Mentored Awards in 2013 and leveraged all CTSI funds with matching University funding. We expect to award a similar number of CTSI Junior Faculty Mentored Awards in 2014. Additionally, we are expanding the scope of the K program to provide resources to this critical juncture in faculty careers.

**Goal 4: Recruit at least 30 CTSI translational research faculty over the next five years to ensure that the UCLA CTSI fulfills its academic research and teaching mission.**

This multidimensional recruitment strategy which is focused on identifying high-impact candidates continues to be robust at each campus.
a. PERSONNEL
Leader: Christopher Denny, MD
Co-leaders: Jonathan Kaye, PhD; Scott Filler, MD
Key personnel: Christopher Evans, PhD; Jay Vadgama, PhD; Noah Craft, MD; Clive Svendsen, PhD; Michael Teitell, MD

b. STRATEGIC GOALS OF PROGRAM
Goal 1: Implement a system for providing centralized access to an ongoing performance monitoring of Translational Technology Resources (TTRs).
Goal 2: Create an efficient mechanism for developing promising new technologies into functional TTRs.
Goal 3: Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs.

c. PROGRAM CHARACTERISTICS
c.1. Process
The process and percent effort of personnel has not changed from the previous year. Dr. Denny (25% effort) plans and coordinates voucher RFAs; creates/maintains a companion database for generating rank-order lists using data from online RFP application; reviews voucher applications; provides feedback and guidance to translational researchers regarding voucher program. Drs. Evans (5%) and Teitell (5%) are voucher application reviewers. Dr. Kaye joined the program as a co-leader from Cedars-Sinai Medical Center, replacing Dr. Jerome Rotter.

c.2. Progress
The CTT continued to support translational researcher’s access and utilization to core services primarily through the voucher program. In this last fiscal year, 255 applications were reviewed and a total of 79 awards were made.

d. MAJOR ACCOMPLISHMENTS BY GOAL

Goal 1: Implement a system for providing centralized access to an ongoing performance monitoring of Translational Technology Resources (TTRs).
This past year marked the first intercampus voucher RFA. A total of 186 applications were received from the four UCLA CTSI campuses. Each application received three reviews: two from reviewers from the same campus and one from a reviewer from a different campus. This effort was made possible by using the upgraded RFP online software package developed at UCLA by the Computer Technology Research Lab.

Goal 2: Create an efficient mechanism for developing promising new technologies into functional TTRs.
Development of new cores progressed along two lines. First, the CTT continues to coordinate efforts with the UCLA Shared Resource Initiative, a program run from the office of the Vice Chancellor for Research. In parallel, the CTT uses the voucher program to identify nascent technologies that may be useful for translational investigators. When completing a voucher application, investigators are free to request technical services that may not yet exist as a free standing core. One example of this is the Wireless Health Institute with whom the CTT is currently working to establish as a core service.

Goal 3: Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs.
The CTT continues to sponsor open house events as a means to communicate and clarify core service related information to translational investigators. These events are broadcasted live across all four campuses and
consist of 10-15 min presentations by individual cores as well as Q/A period regarding upcoming voucher RFAs. Cores that are of particular interest to investigators based on recent voucher application requests are selected for this venue. In this past year, the numerous services offered through the Department of Pathology were highlighted.

e. OPPORTUNITIES AND CHALLENGES
Our External Advisory Board noted three opportunities for improvement, which we discuss below.

- The prior EAB recommendation for user dashboards has been thwarted by university accounting systems to date.

We recognize the benefits of providing investigators with up to date feedback regarding the status of their voucher applications. Even after they are awarded vouchers, investigators frequently have to meet additional administrative requirements before these funds can be used. To address this need, a Web-accessible tracking system will be constructed to enhance communication between investigators, CTSI staff and core directors. Voucher awardees will log into the system to access forms that may be needed prior to spending voucher subsidies, such as addenda to IRB and IACUC protocols. Once completed, the CTSI staff will green light their projects which will serve as an alert to core directors. We look forward to testing version 1 of this tracking system with the next voucher RFA occurring in fall 2013.

- For all CTSI resources and services: consider a shift from scheduled internal RFA’s for use of CTSI resources to continuous ability to catalyze faculty creativity whenever it occurs. Waiting weeks or months to submit to a RFA deadline can be chilling. This would require an ongoing continuous review process, which other CTSA’s have set up, and the ability to track obligations and actual expenditures in a timely and fine-grained fashion.

Without a doubt, the developing an on-demand version of the voucher review is an exciting option worth pursuing. The streamlined review model currently being implemented on the Westwood campus (i.e., a standing board of three reviewers), makes it an ideal location to pilot this program. Reviewing applications within one week of receipt is feasible. Pay lines could be set based on scores from the over 350 applications reviewed from past RFAs.

Potentially the most difficult problem will be logistical. Since these vouchers will be awarded in a temporally random fashion, keeping track of the progress of projects awarded through this mechanism will be challenging. In this regard, the successful development of our online tracking system described above, will be critical. Providing that this system passes muster for the fall 2013 RFA, we would hope to pilot an on demand voucher program in the months following.

- The process for selecting new cores for development could be more transparent and systematic. You may also want to consider development of a process for the elimination of cores that are no longer widely used or cost competitive with outsourcing options.

In one sense, our voucher program is an auto-regulatory system that allows investigators to vote with their feet. Those cores that offer outdated technologies or services that are not in demand, will cease receiving CTSI support. With regard to new core development, the voucher RFA system itself serves as an up to date indicator of what investigators want. In the next RFA iteration, we will expand this further and explicitly query investigators about core services that they feel they need but currently cannot access.

The CTT’s primary responsibility is to stimulate and support translational research, not necessarily to underwrite particular cores. On an annual basis, the technology officer will report and review with CTT leadership, current high usage cores to see if better commercial options exist.

A final challenge is an unexpected drop in voucher applications. It is possible that our earlier RFA rounds have satisfied pent-up demand and applications are now at a normalized level. In the next year, we will increase our
outreach and counseling efforts, and closely monitor the impact of an “on-demand” voucher scheme on application volume.

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE
None.

g. PLANS FOR COMING YEAR BY GOAL

Goal 1: Implement a system for providing centralized access to an ongoing performance monitoring of Translational Technology Resources (TTRs).
As noted above, we plan to pilot a Web-accessible tracking system to enhance communication between investigators, CTSI staff and core directors. Voucher awardees will log into the system to access forms that may be needed prior to spending voucher subsidies, such as addenda to IRB and IACUC protocols. The system will also allow awardees to track expenditure of voucher awards.

Goal 2: Create an efficient mechanism for developing promising new technologies into functional TTRs.
We currently are working with the UCLA Wireless Health Institute to develop a sales and service agreement so it may offer core services to the CTSI community. We expect this agreement will be reached and the core will become operational in year 4.

Goal 3: Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs.
In year 4, we plan to improve feedback to voucher applicants, particularly those that are not funded. This will be done by providing more information from the review in a semi-automated fashion. At the same time, we will prospectively offer “office hours” for those investigators that wish to discuss their past and future applications in more depth. As always, support for junior investigators will be emphasized.
a. PERSONNEL

Leader: Douglas Bell, MD, PhD
Co-leaders: Paul Fu, Jr., MD, PhD; Omolola Ogunyemi, PhD; Spencer SooHoo, PhD
Key personnel: Arash Naeim, MD, PhD; Alex Bui, PhD; Denise Aberle, MD; Robert Dennis, MD; Virginia McFerran, MD

b. STRATEGIC GOALS OF PROGRAM

Goal 1: Expand and amplify our established Virtual Home (VH), the CTSI’s Internet portal

Goal 2: Establish a Research Data Repository (RDR), a Common Terminology Service (CTS) to support data harmonization and interoperability, and a Clinical Trials Management System (CTMS)

Goal 3: Provide training in informatics tools and methods

c. PROGRAM CHARACTERISTICS

c.1. Process

Dr. Douglas Bell (60% effort) continues to lead the Biomedical Informatics Program, along with the informatics co-leaders at each partner site, Drs. Fu (Harbor-UCLA/ LA Biomed, 9% effort), Ogunyemi (Charles Drew University of Medicine and Science, 15% effort), and SooHoo (Cedars-Sinai Medical Center, 10% effort).

BIP has continued to leverage relationships with other units at UCLA to achieve its goals, including partnership with the UCLA Health System in developing the Integrated Clinical and Research Data Repository (xDR), the UCLA Academic Technology Service (ATS) in hosting the UC-Research eXchange (UC-ReX) data repository systems, and the David Geffen School of Medicine in hosting the Virtual Home and in establishing an organizational home for the CTMS.

c.2. Progress

BIP has made substantial progress toward each of its goals. Toward Goal 1, we completed implementation of the Team Science System (TSS), our service request system, activating it for all UCLA CTSI program areas and our partner sites. Toward Goal 2, we achieved key milestones for several data repository systems. An initial version of xDR was established, enabling research access to UCLA Health System data. UC-ReX was launched, enabling clinical investigators to identify potential research study cohorts across the five UC medical centers. The Los Angeles Data Resource (LADR) Consortium was negotiated and entered into by the two largest CTSI partners, Cedars-Sinai Health System and UCLA Health System, creating a pooled repository of linked clinical data for region-wide research. Toward Goal 3, we inaugurated the Informatics Module for the Training Program in Translational Science, training approximately 40 individuals.

d. MAJOR ACCOMPLISHMENTS BY GOAL

Goal 1: Expand and amplify our established Internet portal (Virtual Home; VH)

BIP provides Web services and support to the CTSI Office of the Institute, which oversees the content and design of the VH and the service request system (Team Science Workflow System; TSS) through which investigators access CTSI resources and expertise (see Highlights section). In collaboration with the Office of the Institute, year 3 enhancements include broad implementation of the TSS to track and facilitate CTSI service requests, and integration with the UCLA Profiles database, enabling researchers to edit their own profiles.

As of Nov. 4, 2013, 627 people created TSS accounts, enabling them to place service requests, edit their profiles, verify publications, and complete service evaluations. From Jan. 1 to Nov. 14, 2013, 473 service
requests were submitted—half of them by investigators. The requests translated into 521 service tickets (a request may involve more than one service). The majority of requests (388) were assigned to a CTSI service provider and 5% of them (19) were multidisciplinary in that they involved more than one service provider program. The most frequently used service combinations in multidisciplinary requests were (1) Biostatics and Biomedical Informatics and (2) Community Engagement and Grant Submission Facilitation.

**Goal 2: Establish a Research Data Repository (RDR), a Common Terminology Service (CTS) to support data harmonization and interoperability, and a Clinical Trials Management System (CTMS).** BIP has made major progress on three distinct RDR projects: UCLA Health System xDR, Los Angeles Data Resource (LADR), and UC Research Exchange (UC-ReX).

- UCLA Health System launched its Epic EHR system on 3/1/13, and the xDR became operational for providing health system data over the ensuing months. To date, the BIP team has supported 12 research studies in obtaining access to xDR data, advising on Institutional Review Board language and assisting investigators with fleshing out their data requests and establishing the infrastructure for extracting data into REDCap and other appropriate databases.

- For LADR, the terms of participation and governance were negotiated and formalized in a legally binding participation agreement. To date, UCLA Health System and Cedars-Sinai Health System have joined the LADR Consortium by signing the agreement. Participation is being considered by the University of Southern California, Children’s Hospital Los Angeles, Charles Drew University, and Los Angeles County Department of Health Services, which represents our CTSI partner Harbor-UCLA Medical Center. Technical development is now underway, with initial launch expected by March 2014.

- Implementation of the UC-ReX system was completed and access to the system was launched for investigators across all five UC medical campuses in October 2013. The system gives investigators self-service access to count data from approximately 12 million patients. At UCLA, 61 individuals have received training and received user accounts. Since the launch date 218 queries have been run and one investigator has submitted an NIH proposal that was supported by data retrieved from UC-ReX.

In year 3 UCLA began a major restructuring of its systems for managing clinical trials. Arash Naeim, MD, PhD was appointed Chief Medical Officer for Clinical Research. Under his purview, a Clinical Trials Informatics Office was created, with responsibility for the selection and implementation of a CTMS. They have selected OnCore by Forte Research Systems, and they are currently in the planning stages for initial implementation in January 2015 and full implementation in June 2015.

BIP is also supporting the REDCap data collection system for research data and CTSI investigators are being directed to use REDCap where possible rather than Excel spreadsheets, access databases, or other ad hoc data collection methods. Liz Chen at Harbor-LA Biomed, who has the greatest experience with the system, is serving as the lead educator for REDCap users. The REDCap instance at Harbor-LA Biomed has 40 projects in production, 34 projects in development and 15 projects completed and archived. UCLA has 9 projects in production, 67 in development and 3 completed and archived. Only 6 of these projects had been initiated prior to June 2012. CDU has 13 projects in production, 9 in development and 1 completed and archived.

**Goal 3: Provide training in informatics tools and methods.** BIP launched the 5-part Informatics Module for the Training Program in Translational Science, which delivered a total of 9 hours of informatics training to approximately 40 individuals. Of all attendees, 42% rated the module “excellent” 37% rated it “above average.” The BIP team has also trained numerous individuals on our newly launched tools: 56 individuals have been trained on the TSS and 61 individuals have been trained on UC-ReX. We are also working with the CTSI Biostatics Program and the Clinical and Translational Research Center to develop ongoing REDCap training.
e. OPPORTUNITIES AND CHALLENGES

We collaborated with the CTT program to evaluate implementation of the eagle-i resource discovery system but we decided it did not add sufficiently to our currently functional site for accessing core services. We are still considering eagle-i among our priorities for Year 4. Our timeline for the LADR project was delayed due to extensive negotiation with Cedars-Sinai but we are now on track to launch an initial version in the upcoming quarter. Our plans for a study for comparing patient linkage algorithms have also been delayed due to ongoing negotiations with our LA County partner organization. We now expect to complete this study by early 2015.

This year, the CTSI External Advisory Board (EAB) expressed satisfaction with the BIP’s progress on its stated goals. In addition, they posed the new challenge of creating a single department or research unit to organize the informatics faculty and informatics training efforts. In response, the Dean’s Office convened a Biomedical Informatics Task Force to make recommendations regarding the creation of a department or organized research unit for biomedical informatics. We expect that the resulting unit will strengthen the role of BIP in providing training and support for translational research. We also expect to be creating an ACGME-accredited clinical informatics fellowship in 2014, which will provide another source of trainees for informatics projects.

f. MODIFICATIONS TO PROGRAM PLAN, ACTIVITIES OR FOCUS WITH RATIONALE. None

g. PLANS FOR COMING YEAR BY GOAL

Goal 1: Expand and amplify our established Internet portal (Virtual Home). In collaboration with the Office of the Institute, we will continue to expand the VH, increase the use and usability of TSS, and improve response rates to followup surveys. We plan to complete a study of our profiles system and to begin migrating it to the Vivo platform. We will also be developing a system to synchronize profiles with our partner Charles Drew University, which maintains its own implementation of the Harvard Profiles system. In collaboration with the University of California Center for Accelerated Innovation (UC CAI), we plan to re-examine the use of eagle-i for enhancing discovery and utilization of core services across all five UC medical campuses.

Goal 2: Establish a Research Data Repository (RDR), a Common Terminology Service (CTS) to support data harmonization and interoperability, and a Clinical Trials Management System (CTMS)

- For xDR, we will complete implementation and establish an automated process for investigators to obtain health system data for studies. We will complete development of our cohort recruitment process, with data from xDR feeding into study-specific recruitment databases, primarily using the REDCap system, where access to protected health information can be appropriately controlled. LADR will launch for UCLA and Cedars-Sinai investigator in spring 2014. We will work to recruit LADR participation from USC, CDU, Los Angeles County Department of Health Services, and Children’s Hospital Los Angeles.

- We will continue to refine and add to the data contained within UC-ReX. All three data repository projects will support investigators in applying for grants, in gaining access to data for analysis, or in recruiting patients for clinical trials.

- For CTMS, we expect OnCore implementation to be nearly completed by the end of Year 4, with initial go-live ready for Jan. 2015.

Goal 3: Provide training in informatics tools and methods. We will work with the School of Medicine to develop an ACGME-accredited informatics training program in clinical informatics. We will also partner with the CTSI Biostatics Program and other informatics-related training programs at UCLA, such as the Bioinformatics Interdisciplinary Program, the Computational Biology Initiative and the Imaging Informatics Program of the Department of Radiology to develop more extensive course work for biomedical informatics trainees. BIP will also continue to offer the Informatics Module for the Training Program in Translational Science to investigators and will continue to provide training on all informatics tools supported by BIP.
a. LEADERSHIP
Leader: Carol Mangione, MD, MSPH
Co-leaders: Mitchell Wong, MD, PhD; Linda L. Demer, MD, PhD; Katrina N. Dipple, MD; Ronald Edelstein, EdD; Leon Fine, MD; Isidro Salusky, MD; Ren Sun, PhD; and Christina Wang, MD
Key personnel: Luann Wilkerson, EdD; William Cunningham, MD, MPH; Pamela Davidson, PhD, MSHS; and Susan Ettner, PhD

b. STRATEGIC GOALS OF THE PROGRAM
Goal 1: Optimize cross-disciplinary training and integrate community input into research training activities throughout the CTSI through the CTSI-ED Office.
Goal 2: Transform translational education through new curricular elements in highly successful existing programs and create new programs incorporating community engagement and interdisciplinary methodologies and technologies.
Goal 3: Provide mechanisms to integrate patient-oriented research training through a course menu, expansion of didactic programs (the CTSI Curriculum Tree) and an integrated assessment program providing a sophisticated, computer-based, learning management system.

c. PROGRAM CHARACTERISTICS
c.1. Process
Dr. Mangione (35% effort) directs the daily operations of the CTSI-ED Office with the assistance of Dr. Wong (20% effort), who also directs the KL2 Program. Assisting them are co-leaders Drs. Demer (2.5% effort), Dipple (10% effort), Edelstein (5% effort in kind), Fine (10% effort in kind), Sun (5% effort), Wang (6.75% effort). Dr. Ettner (15% effort) directs the TL1 Program for graduate students and Dr. Cunningham (10% effort) directs the TL1 summer program for professional students. Dr. Salusky (22% effort) is director of the Training Program in Translational Science (TPTS); Drs. Wilkerson (5% effort in kind) and Davidson (5% effort) complete the leadership as the lead evaluators. Ms. Lisa Chan (100% effort) is the program administrator for the CTSI-ED Office and Mr. William Lee (25% effort) provides administrative support to Drs. Mangione and Wong. CTSI-ED faculty are members of the multi-disciplinary Clinical Research Education and Specialized Training (CREST) Committee, which has representation from all four CTSI partners in basic, clinical, health services, and community-partnered research as well as community representatives from the large multi-ethnic urban community in Los Angeles. The CREST Committee provides the organizational structure and forum to discuss cross-institutional collaboration for the different programs under the CTSI-ED and is co-chaired by Drs. Mangione and Wong. The committee meets on the third Tuesday of the month with electronic or personal communications between meetings.
c.2. Progress
The CTSI-ED office continues to operate efficiently under direction of Drs. Carol Mangione and Mitchell Wong with administrative support from Ms. Lisa Chan and Mr. William Lee. Our Year 2 activities include: KL2 & TL1 Programs, K Bridge Award, TPTS, Curriculum Tree, High School Pipeline Manuscript, Long Beach Polytechnic High School Biomedical Research Program, Minority Aging Research Collaboration, Grant Writing Workshops, and DGSOM/CTSI Mentors Advisory Committee. See below for more details.

d. MAJOR ACCOMPLISHMENTS BY GOAL
- **KL2 & TL1 Programs (Goals 1 & 2).** In Year 3, the CTSI-ED successfully selected 3 new KL2 Translational Science Scholars, 5 new TL1 Translational Science Pre-doctoral Fellow and 12 TL1 Summer Professional Students. By negotiating departmental and institutional matching funds, we expanded the KL2 and TL1 programs to include: 5 additional KL2 Scholars and 8 additional TL1 Summer Professional Students. (Please see the KL2 and TL1 Program Reports elsewhere in this report for more details).
- **K Bridge Award (Goals 1 & 2).** This new funding opportunity is designed to help junior faculty who have submitted unsuccessful individual K grant applications (or equivalent) by providing additional time for productivity as they strengthen their proposal for resubmission. In Year 3, we awarded three K Bridge
recipients, two from the KL2 grant and the other from departmental/institutional matching funds. (Please see the KL2 Program Report elsewhere in this report for more details).

- **TPTS (Goal 2).** The Training Program in Translational Science (TPTS) remains under the direction of Dr. Isidro Salusky. The TPTS continues to offer 3 Tracks: 1) Workshops, 2) Certificate Program, 3) Masters of Science in Clinical Research (MSCR), and also offers a Medical Student Pathway in Clinical and Translational Research. Currently, 112 trainees are enrolled in Track 1 (including 23 new applicants in 2013), 26 in Track 2 (20 of them new in 2013), 23 in Track 3 (6 are new in 2013), and 82 medical students (21 are new in 2013). Since 2001, 246 trainees have enrolled in Tracks 2 and 3 and 62% of them have completed their programs to obtain either the Certificate or MSCR. In addition to four new training modules in Track 1 on comparative effectiveness research, we added a nine-hour biomedical informatics module that covers informatics in healthcare and translational research, community-based informatics research, data standards and terminologies (emphasizing both electronic health record systems and clinical decision support), and practical tools (such as REDCap).

- **Curriculum Tree (Goals 1 & 3).** To meet our goal of integrating our cross-disciplinary training across the four CTSI institutions, we created a virtual home for the CTSI Curriculum Tree using Moodle, a computer-based learning management system. This system allows us to provide online access to translational science curriculum, course material, and implementation of core competency evaluations. Moodle will allow us to implement more courses via distance learning. As of fall 2013, we implemented Moodle for all TPTS modules/courses, finalized the UCLA CTSI core competencies, and mapped all TPTS curriculum to these competencies. We have also started to include curriculum outside of the TPTS, such as the Robert Wood Johnson Foundation Clinical Scholars Program’s seminars on improvement methods and survey design. In collaboration with the Bioinformatics Program (BIP) and Evaluation Program, we installed the feedback module and launched all TPTS course evaluations via Moodle at the end of fall 2013. As a result of the distance-learning capabilities of Moodle, TPTS trainees from the partner institutions increased by 38%.

- **High School Pipeline Manuscript (Goal 2).** The High School Pipeline Working Group, led by CTSI-ED faculty Drs. Mangione and Mitchell Wong, convened to discuss collaborative opportunities to expand the existing programs: CDU Saturday Science Academy, CDU NIH Short-Term Education Program for Underrepresented Person (STEP-UP), CDU Project STRIDE, LA BioMed Summer Fellowship Program, Long Beach Polytechnic High School (Cedars & LA BioMed), UCLA Brain Research Institute Outreach, UCLA Community School, UCLA Pre-Medical/Pre-Dental Enrichment Program (PREP), UCLA Re-Application Program (RAP), UCLA Howard Hughes Medical Institute Pre-College Science Education Program, and UCLA Department of Medicine Chief Residents’ Program. A manuscript on best practices and long-term outcomes across the existing pipeline has been drafted and is currently under review by Drs. Mangione and Wong. The goal is to submit this manuscript for publication in a peer-reviewed journal by the end of Year 4.

- **Long Beach Polytechnic High School (LBPHS) Biomedical Research Program (Goal 2).** In partnership with LBPHS, this program has been expanded and CTSI will now bring students to UCLA Westwood, in addition to Cedars-Sinai and LA BioMed. Five students have been assigned to UCLA and will be mentored by two current KL2 Scholars, Drs. David Shackelford and Anne Walling from December 2013 to February 2014. At the end of the program, students will prepare a poster for presentation at the final poster session held at Cedars-Sinai.

- **Minority Aging Research Collaboration (Goals 1 & 2).** The CTSI continues its strong collaboration with the UCLA/CDU Resource Centers for Minority Aging/Center for Health Improvement for Minority Elders (RCMAR/CHIME) to co-fund 3 pilot investigators in 2013 to conduct Type 2 translational research focused on minority aging research. Since the spring of 2012, 10 RCMAR/CHIME pilot investigators were co-funded by the CTSI. As a group, they have published 18 peer-reviewed manuscripts during this reporting period. The CTSI will continue to provide co-funding for 3 pilot investigators per year. RCMAR/CHIME holds tri-annual Scientific Retreats (attended by faculty, trainees, community partners) and offer monthly Methodological Seminars focused on health disparities research. Trainees may submit writing drafts (i.e. manuscripts, proposals) to be reviewed by senior faculty and discussed at the Retreats. These meetings also provide a venue for the trainees to meet community partners and local stakeholders. This collaboration has also been a catalyst in developing and strengthening our relationship with CDU. Two KL2 scholars and 3 TL1 summer trainees attended the June 17, 2013 Scientific Retreat. Two KL2 scholars, two TL1 pre-doctoral fellows and eight TL1 summer trainees participated in the October 21, 2013.
Scientific Retreat. Scholars and trainees had the opportunity to meet with community partners such as: Health African American Families II, Avalon-Carver Community Center, Hollywood Senior Multipurpose Center, County of Los Angeles Community and Senior Services, Oasis Pacific Region, City of Los Angeles Department of Aging, and Watts Labor Community Action Committee. Twenty-two posters were presented at the October Scientific Retreat, ten of which were from CTSI KL2 scholars and TL1 trainees. All of the CTSI trainees participate in the CREST Committee Meetings where they present their work in progress to leading faculty from our 4 institutions.

- **Grant Writing Workshops (Goals 1 & 2).** We held two all-day K/Career Development Award (K/CDA) Workshops in 2013: January 10th at LA BioMed and July 25th at UCLA Westwood. The next workshop will be hosted at Cedars-Sinai on February 13, 2014. In addition to the K/CDA Workshop, we have developed an all-day K to R Transition Workshop to teach investigators about how to plan and craft sections of the R grant applications and what study section reviewers look for. (Please see the KL2 Program Report elsewhere in this report for more details). In collaboration with Cedars-Sinai faculty, Dr. Salusky developed a two-week course (1 week at UCLA and 1 week at Cedars) called “Clinical & Translational Research Workshop: Grant & Clinical Protocol Development.” The course was held for the first time in July 2013 with 33 trainees enrolled, and is expected to be offered each summer.

- **David Geffen School of Medicine (DGSOM)/CTSI Mentors Advisory Committee (Goals 1 & 2).** With the support of Dr. Jonathan Hiatt, Vice Dean of Faculty at DGSOM, Drs. Mangione and Wong have assembled a committee focused on improving the quality of mentorship and subsequently increasing the number of career development awards submitted and awarded. The chair of this committee is Dr. Judith Currier, Division Chief of Infectious Diseases at UCLA, and members are made of elite and accomplished investigators from all CTSI partners with a track record of academic success, both in their own careers and in the career of their trainees. This group will lead the initiative’s development and provide critical feedback on implementation and evaluation. The first committee meeting was convened on November 12, 2013 to review the goals of the initiative. The committee aims to have recommendations by the end of Year 4 and the representatives from the CTSI partners can bring them back to their institutions for consideration.

e. **OPPORTUNITIES AND CHALLENGES IN IMPLEMENTING RELEVANT PROGRAM ACTIVITIES**

There have been significant challenges with expanding the UCLA STAR Program to CTSI partners. The main barrier is the cost of tuition for the UCLA degree. Fellows with a paid UCLA academic appointment receive a two-thirds fee reduction but trainees at CDU, Cedars-Sinai and LA BioMed do not. We will continue to work with the CTSI leadership and UCLA Graduate Division to resolve the issue.

f. **MODIFICATIONS MADE TO ORIGINAL PLAN, ACTIVITIES OR FOCUS WITH RATIONALE**

There have been no major modifications to the original plan.

g. **PLANS FOR COMING YEAR**

**Goal 1: Continue to integrate community input and involvement into research training activities.**

- Encourage more CTSI KL2 scholars and TL1 trainees to participate at the CTSI/RCMAR/CHIME Scientific Retreats to network with community partners, who may serve as community mentors for each TL1 dissertation committee and each KL2 project where appropriate

**Goal 2: Continue to transform translational education. Our objective in year 4 will be to develop programs to increase the number of faculty who apply for and receive career development awards.**

- Organize information sessions on Diversity Supplements to help strengthen the goal of maintaining diversity in the pipeline.
- Collaborate with DGSOM Dean’s Office to evaluate the global application and success rate for K grants.
- Develop workshops to teach trainees about approaches to diversify resources of non-federal support.
- Brainstorm and strategize with the DGSOM/CTSI Mentors Advisory Committee to develop plans on how to increase the number of career development awards submitted and awarded at all UCLA CTSI institutions.

**Goal 3: Continue to provide mechanisms to integrate research training through the CTSI Curriculum Tree.**

- Expand Moodle to include translational science curriculum outside of the TPTS, particularly in the basic science and health services research by the end of Year 4.
- Develop a system to monitor and evaluate processes and outcomes of the distance-learning technologies.
UCLA CTSI
KL2 Scholars Program
Annual Progress Report (Year 3)

a. Leadership
Leader: Mitchell D. Wong, MD, PhD
Co-leaders: Carol M. Mangione, MD, MSPH, Linda L. Demer, MD, PhD; Katrina N. Dipple, MD; Ronald Edelstein, EdD; Leon Fine, MD; Isidro Salusky, MD; Ren Sun, PhD; and Christina Wang, MD
Key personnel: Luann Wilkerson, EdD; William Cunningham, MD, MPH; Pamela Davidson, PhD, MSHS; and Susan Ettner, PhD

b. Strategic Goals of the Program
Goal 1: Recruit outstanding scholars with the potential to become leaders in translational science
Goal 2: Identify individualized training opportunities to deepen scholars’ expertise in translational research and provide the training necessary to become successful independent researchers.
Goal 3: Assist scholars with developing and submitting proposals for individual career development (e.g., K23) or independent investigator-initiated grants (e.g., R01) funded by the NIH or another agency.

c. Program Characteristics

   c.1. Process
Dr. Mitchell Wong (20% effort) is the Director of the UCLA CTSI KL2 Translational Science Scholars Program under the CTSI-ED, which he also co-directs with Dr. Carol Mangione (35% effort). Ms. Lisa Chan (100% effort) is the program administrator and Mr. William Lee (25% effort) provides administrative support.

   c.2. Progress
Expansion of the KL2 Program. We awarded three new KL2 Scholars from an outstanding pool of 38 applicants: 13 from basic science, 12 from clinical research and 13 from health services research. With institutional/departmental commitment, we were able to fund an additional five KL2 Scholars, expanding the 2013 cohort from three to eight scholars. They have strongly committed mentors who are receptive to adding CTSI mentors to each scholars’ multidisciplinary mentorship team as needed to strengthen the science. (Please see the Scholars Progress Reports elsewhere in this report for more details.) Of the 2013 applicants, 47% were male; 53%, female; and 13%, minority. Applications from partner institutions rose in 2013 by the following percentages: Cedars-Sinai, 17%; CDU, 67%; and LA BioMed, 40%. We continued to use an online submission process and convened a Selection Committee with representation from all CTSI partners.

K Bridge Award. With funds from the KL2 grant and institutional support, the CTSI-ED has created a K Bridge Award for junior faculty who received a competitive score on an NIH individual K award grant application did not meet the cutoff for funding. Bridge Awards provide recipients with additional time for productivity to strengthen their proposal for resubmission. Three K Bridge Scholars, Drs. Alma Guerrero, Elizabeth Marcus and Laura Payne, were selected in 2013. (Please see the Scholars Progress Reports elsewhere in this report for more details).

NIH K/Career Development Award Workshop. Due to high demand for the NIH K/Career Development Award Workshop, we held two more workshops in 2013: one at LA BioMed Harbor-UCLA (January 10th) and one at UCLA Westwood (July 25th). The morning session of this K Award Workshop featured presentations by senior leadership on the following topics: an overview of CTSI resources, navigation of the NIH K award process, development of NIH K award proposals, perspectives from the NIH study sections, and familiarization with the UCLA CTSI KL2 award process. The speakers included: Dr. Steven Dubinett, Carol Mangione, Isidro Salusky, Christina Wang, David Meyer, and Mitchell Wong. During the afternoon session of the workshop, senior faculty reviewed and discussed draft applications submitted by junior investigators and provided feedback on how to improve their K/CDA applications. In 2013, the workshops were attended by over 90 junior investigators from all CTSI partners and 27 of them submitted draft K/CDA applications for review. We conducted pre and post surveys, which show that these workshops continue to be very well received (see diagram below for compiled data since 2012). The junior investigators who participated in the review/discussion session of draft applications found it very beneficial to meet with their reviewers and get in-person feedback.
K to R Workshop. We organized this first all-day workshop on December 12, 2013 for investigators to learn how to plan and prepare successful R grant applications. The morning session included presentations and panels on the following topics: preparation for R grant applications; crafting the innovation, significance and sections; and perspectives from the study sections. The panelists and speakers are represented by senior scientists with backgrounds across the translational science spectrum from the UCLA Schools of Medicine (Drs. Carol Mangione, Steven Dubinett, Jonathan Hiatt, David Elashoff) and Dentistry (Dr. Vivek Shetty), LA BioMed at Harbor-UCLA (Dr. Scott Filler), and RAND Santa Monica (Dr. Joan Tucker). In the afternoon, seven participants gave presentations in review group sessions about the plan for their R grant application, and senior faculty provided feedback on how to improve the plans to make stronger R grant applications.

d. Major Accomplishments by Goal

Goal 1: Recruit outstanding scholars with the potential to become leaders in translational science.
We continue to recruit outstanding scholars, especially with the expansion of the KL2 Program and the creation of the K Bridge Award. During this reporting period, one KL2 and one K Bridge Scholar exited the program. KL2 Scholar Dr. Joshua Zaritsky accepted an academic position as Associate Professor of Pediatrics in the Division of Pediatric Nephrology at Nemours/A.I. Dupont Hospital for Children in Delaware. K Bridge Scholar Dr. Alma Guerrero received her K23 through the NIH/NICHD. As a group, the 16 KL2 and K Bridge Scholars had a total of 32 peer-reviewed publications during this reporting period.

Goal 2: Identify individualized training opportunities to deepen scholars’ expertise in translational research and provide the training necessary to become successful independent researchers.
Dr. Wong and the primary mentors work closely with the KL2 Scholars to help identify the best educational programs that will expand their knowledge and expertise. For example, Dr. James McKinnell is pursing the Masters of Science in Health Policy and Management (MSHPM) through the UCLA School of Public Health. The other scholars continue to take individual courses at UCLA as well as workshops/seminars available through their department or annual professional conferences. A few of them are working with Dr. Isidro Salusky, director of the CTSI Training Program in Translational Science (TPTS), to see whether they should enroll in Track 2 (Certificate) or Track 3 (MSCR) in addition to what they have proposed in their career development plan.

Goal 3: Assist scholars with developing and submitting proposals for individual career development (e.g., K23) or independent investigator-initiated grants (e.g., R01) funded by the NIH or another agency.
As noted above, we held two NIH K/Career Development Award Workshops this reporting period with the goal to help junior investigators understand the development and submission process of career development awards. We also launched a six-month follow-up survey since the first workshop in July 2012 and 26% of the respondents indicated that they have submitted a K/CDA application and 63% of those applications were submitted to the NIH. 38% of those submitted K/CDA applications were funded, 20% of which were funded by the NIH. An additional 19% of the respondents indicate that they plan to submit an application within the next 12 months. As noted in the CTSI-ED Report, the CTSI in collaboration with UCLA/CDU RCMAR/CHIME & Project EXPORT holds tri-annual Scientific Retreats, which include review/discussion sessions of draft proposals. Dr. James McKinnell submitted his draft NIH/NIAID K23 proposal for review at the June and
October retreats and reviewers saw significant improvements from the first and second drafts. As noted above, we have selected two K Bridge Scholars during this reporting period and one of them, Dr. Alma Guerrero, has been awarded a K23. We have also launched the first K to R Workshop on December 12, 2013 at UCLA Westwood. Forty-five investigators are registered for this event and seven of them submitted their R grant application plans for review.

e. Opportunities and Challenges in Implementing Relevant Program Activities
In response to the External Advisory Board (EAB) recommendations, we have developed the K to R Workshop to help investigators learn about when and how to prepare for their first R grant applications. Due to the time needed for planning and recruiting reviewers for the NIH K/CDA Workshops, we have only been able to hold two per year instead of quarterly. During the 2013-14 academic year, we plan to add a longitudinal component to the K/CDA Workshops to offer continuous one-on-one mentorship between the workshops. To implement this program, we need to identify a cadre of advisors/mentors across a wide array of disciplines that are willing to participate. To initiate this program, we have linked junior investigators outside of the K/CDA workshop to senior faculty who can provide written reviews for their draft proposals.

f. Modifications Made to Original Plan, Activities or Focus with Rationale
There have been no major modifications to the original plan.

g. Plans for Coming Year

Goal 1: Recruit outstanding scholars with the potential to become leaders in translational science
- Expand the KL2 Program with continued institutional and departmental support for junior investigators to conduct translational research.
- Maintain constant communication with the education leaders at Cedars-Sinai, CDU and LA BioMed to better market the KL2 program and continue in-person visits to the different CTSI institutions to recruit and encourage junior investigators to apply for the program.
- Collect and review demographic information to ensure that this program is recruiting, enrolling and mentoring under-represented junior faculty. Explore additional partnerships with centers and programs that focus on minority faculty development in basic science, such as the CDU Accelerating Excellence in Translational Science (AXIS), Research Centers in Minority Institutions (RCMI) and RCMI Translational Research Network (RTRN).

Goal 2: Identify individualized training opportunities to deepen scholars’ expertise in translational research and provide the training necessary to become successful independent researchers.
- Continue to work with the KL2 scholars and their mentors to determine which educational opportunities would benefit their career and research, such as the Masters in the Science of Clinical Research (MSCR), the Masters in Science of Health Policy and Management (MSHPM), and/or participation in the CTSI Translational Science Training Program (TPTS) workshops and certificate tracks.
- Increase formal career mentoring for KL2 scholars to help with their transition to becoming independent scientists by encouraging attendance to the K to R Workshop. Afterward, we hope to make some parings that will continue to meet with the scholar over the course of award.

Goal 3: Assist scholars with developing and submitting proposals for individual career development (e.g., K23) or independent investigator-initiated grants (e.g., R01) funded by the NIH or another agency.
- Offer the “K/CDA Workshops” and “K to R Workshops” twice per year to provide mock study sections and early grant reviews from senior faculty. The location of the workshops will be rotated between the four CTSI partner institutions.
- Increase the number of K/CDA and R grant submissions by workshop attendees with a goal that 40% of them will get funded after two rounds.
- Increase the number of KL2 scholars to participate in grant writing courses: CTSI K/CDA and K to R Workshops, Clinical & Translational Research Workshop, UCLA/CDU RCMAR/CHIME & CDU/UCLA Project EXPORT Scientific Retreats and monthly Methodological Seminar Series. 65% of the KL2 scholars participated in these courses and we aim to increase their attendance by 50% in Year 4.
- Create a longitudinal component to the K/CDA Workshops to offer continuous one-on-one mentorship between the workshops.
a. Leadership

Leaders: Susan Ettner, PhD and William Cunningham, MD, MPH

Co-leaders: Carol Mangione, MD, MSPH, Mitchell Wong, MD, PhD; Linda L. Demer, MD, PhD; Katrina N. Dipple, MD; Ronald Edelstein, EdD; Leon Fine, MD; Isidro Salusky, MD; Ren Sun, PhD; Christina Wang, MD

Key personnel: Luann Wilkerson, EdD and Pamela Davidson, PhD, MSHS

b. Strategic Goals of the Program

Goal 1: Recruit and select the most competitive candidates from a diverse pool of applicants to conduct health services and health disparities research.

Goal 2: Provide trainees with investigative skills required to expand their knowledge about health services, health disparities, and the theory and methods of conducting community-partnered research.

Goal 3: Recruit the most qualified faculty as mentors for trainees and foster interactions between fellows and faculty.

c. Program Characteristics

c.1. Process

Dr. Susan Ettner (15% effort) is the Program Director of the UCLA CTSI TL1 Pre-doctoral Fellowship. Dr. William Cunningham (10% effort) is the Program Director of the UCLA CTSI TL1 Summer Fellowship for Health Professional Students. Both fellowships fall under the Research Education, Training, and Career Development Program, which is directed by Drs. Carol Mangione (35% effort) and Mitchell Wong (20% effort). Ms. Lisa Chan (100% effort) is the program administrator and Mr. William Lee (25% effort) provides administrative support for both of the TL1 programs.

c.2. Progress

We have identified and awarded five new TL1 pre-doctoral fellows from an outstanding pool of 48 PhD applicants in the Department of Health Policy and Management (HPM) at the UCLA Fielding School of Public Health. Twenty-three percent of the applicants were from minority populations, 29% were male and 71% were female. We are currently focusing on identifying the best academic and community mentors for the TL1 trainees. (Please see the Trainee Progress Reports elsewhere in this report for more details.)

Our 2013 TL1 Pre-doctoral Fellows are:

- **Julian Brunner, MPH** was admitted to the doctoral program in Fall 2013.
- **Geoffrey Hoffman, MPH** was admitted to the doctoral program in Fall 2010. His project title is “Using the Disablement Process Model and Person-Environment Fit Theory to Understand Predictors and Outcomes of Falls in Persons 65 and Older in the United States” under the mentorship of Dr. Susan Ettner.
- **Selene Mak, MPH** was admitted to the doctoral program in Fall 2013.
- **Narissa Nonzee, MPA** was admitted to the doctoral program in Fall 2013.
- **Linda Tran, MPA** was admitted to the doctoral program in Fall 2013.

Our 2013 TL1 Pre-doctoral Program Graduates:

- **Erin Hahn, PhD, MPH** (2011 cohort) completed her dissertation and TL1 training in July 2013. She has accepted a two-year post-doctoral fellowship position in Delivery System/Implementation Science in the Department of Research and Evaluation at Kaiser Permanente Southern California.

We have also selected 20 health professional students (medical, dental, nursing) for the TL1 Summer Fellowship from a pool of 31 applicants. 48% of the applicants were from minority populations, 55% were male and 45% were female. The summer trainees are either funded through the CTSI TL1 grant or institutional funding from UCLA and CDU. The 20 trainees were paired with senior research mentors, participated in an 8-week summer didactic program in interdisciplinary and health disparities research, and presented their findings at the DGSOM Josiah Brown Poster Fair (Please see the Trainee Progress Reports elsewhere in this report for more details.)
Our 2013 TL1 Summer Fellows are:

- **Judith Afonta** (CDU MSN), Mentor: Nadereh Pourat, PhD (UCLA)
- **Eric Chen** (UCLA DDS), Mentor: Fariba Younai, DDS (UCLA)
- **Gerardo Flores** (UCLA PhD in Nursing), Mentor: Dorothy Wiley, PhD (UCLA)
- **Marcel Fomotar** (CDU MSN), Mentor: Martin Shapiro, MD, PhD UCLA
- **Sheila Ganjian** (CDU/UCLA MD), Mentor: Patrick Dowling, MD (UCLA)
- **Brian Hui** (UCLA DDS), Mentor: Tara Aghaloo, MD, DDS (UCLA)
- **Phong Huynh** (CDU/UCLA MD PRIME), Mentor: Wendy Slusser, MD (UCLA)
- **Eugen Kim** (UCLA DDS), Mentor: Kathryn Atchison, DDS, MPH (UCLA)
- **Ebony King** (CDU/UCLA MD), Mentor: Jim Hu, MD (UCLA)
- **Eyerus Masho** (CDU MSN), Mentor: Vanessa Miller, DrPH, RN (CDU)
- **Judith McKelvy** (UCLA PhD in Nursing), Mentor: Arleen Brown, MD, PhD (UCLA)
- **Linda Phi** (UCLA DDS), Mentor: Francesco Chiappelli, PhD, MA (UCLA)
- **Kevin Quan** (UCLA DDS), Mentor: Nancy Reifel, DDS, MPH (UCLA)
- **Pardis Rajabi** (UCLA DDS), Mentor: Shane N. White, BDentSc, MA, MS, PhD (UCLA)
- **Raymund Rebong** (UCLA DDS), Mentor: Nadereh Pourat, PhD (UCLA)
- **Dawn Santos** (CDU MSN), Mentor: Vanessa Miller, DrPH, RN (CDU)
- **Samantha Tangchaiburana** (UCLA MSN), Mentor: Adeline Nyamathi, PhD (UCLA)
- **Maria Tobar** (CDU/UCLA MD PRIME), Mentor: Catherine Sarkisian, MD, MSPH (UCLA)
- **Erica Tukiainen** (CDU/UCLA MD PRIME), Mentor: Carol M. Mangione, MD, MSPH (UCLA)
- **Uzoma Uwakah** (CDU MSN), Mentor: Magda Shaheen, MD, PhD (CDU)

**d. Major Accomplishments by Goal**

**Goal 1:** Recruit and select the most competitive candidates from a diverse pool of applicants to conduct health services and health disparities research.

As noted above, we selected and awarded five new TL1 pre-doctoral fellows and 20 summer fellows. Dr. Susan Ettner worked with the Department of Health Policy and Management (HPM) to organize visits from prospective fellows so they have a chance to meet with Public Health, Medicine and CTSI faculty who share similar research interests. Drs. Cunningham and Michael Rodriguez (co-teacher from Project EXPORT) recruited medical students at the David Geffen School of Medicine’s Summer Research Opportunities Fair in February 2013 and strongly encouraged minority students from the CDU/UCLA medical and PRIME programs to apply. 50% of this summer’s fellows were from minority populations (increased by 17% from Year 2), 10% were from the CDU/UCLA MD Program and 15% were from the PRIME, a five-year dual degree program focusing on the development of leaders in medicine who will improve the health care delivery, research, and policy in underserved communities.

**Goal 2:** Provide trainees with investigative skills required to expand their knowledge about health services, health disparities, and the theory and methods of conducting community-partnered research.

For the TL1 PhD students in HPM, the program offers didactic coursework in research methodology, outcomes research, implementation science, biostatistics, health policy, and community-partnered research. In the last year, Dr. Ettner also implemented quarterly group meetings with the pre-doctoral fellows, which provide a forum for the trainees to talk about any obstacles that they may have encountered. These meetings have evolved into peer mentoring sessions where the second- and third-year pre-doctoral fellows provide guidance to the first-year fellows on the best classes to take for their doctoral degree. As a result of these meetings, the pre-doctoral fellows have decided to start an online catalog of their classes to share with each other and future cohorts.

For the summer trainees, Drs. Cunningham and Rodriguez continue to teach the eight-week seminar series focused on health disparities research. These seminars also allow for interdisciplinary exchange of ideas since the class includes medical, dental and nursing students.
**Goal 3:** Recruit the most qualified faculty as mentors for trainees and fostering interactions between fellows and faculty.

We continue to use our pool of 25 UCLA SPH-HPM faculty affiliated with the CTSI, who may potentially serve as mentors and/or dissertation chairs for the TL1 pre-doctoral fellows. Dr. Cunningham personally recruited 33 faculty members from different institutions, schools, and departments, who were willing to mentor TL1 summer trainees. The TL1 summer trainees also presented their posters at DGSOM Josiah Brown Fair in August 2013, which gave them the opportunity to interact with faculty and students from the different health professional schools at UCLA and CDU. As noted in the CTSI-ED Report, all CTSI trainees were invited to attend and participate in the Scientific Retreats, which were held on June 17 and October 21. For the October 21 retreat, one TL1 pre-doctoral fellow and six summer fellows presented their work during the concurrent poster sessions and got valuable feedback from faculty and community partners. Three of the TL1 pre-doctoral fellows participated in the K Award Workshops held on January 10 and July 25.

e. Opportunities and Challenges in Implementing Relevant Program Activities

For the TL1 summer program, we worked with the curriculum committee in School of Dentistry (SOD) to schedule the health disparities seminars during a time when their students were able to participate. The seminar schedule is still a challenge for the dental students as they have a mandatory summer curriculum for their DDS in addition to the fellowship. We will continue to work with SOD to develop a plan that allows their students to participate.

We also encountered challenges with summer trainee eligibility for the MSN and PhD nursing students at CDU and UCLA. The TL1 program requires that the trainees are pursuing a health professional doctoral degree but cannot hold a masters degree in health sciences. We had two highly qualified PhD nursing students at UCLA and six MSN students from UCLA and CDU who were ineligible per TL1 eligibility requirements. We negotiated with the deans of the UCLA and CDU Schools of Nursing to secure institutional funding for these eight students to participate in the program along with the 12 TL1-funded summer trainees.

f. Modifications Made to Original Plan, Activities or Focus with Rationale

There have been no major modifications to the original plan.

g. Plans for Coming Year

**Goal 1:** Continue to recruit and select the most competitive candidates from a diverse pool of applicants to conduct health services and health disparities research.
- Maintain strong communication with the education leaders and deans at CDU and UCLA to better advertise and increase the number of applications from health professional students for the TL1 Summer Program.
- Collaborate with the SOD Curriculum Committee to tailor a TL1 Summer Program schedule that would work best for the dental students.
- Collect and review demographic information to ensure that this program is recruiting, enrolling and mentoring under-represented pre-doctoral and health professional students.

**Goal 2:** Continue to provide trainees with investigative skills required to expand their knowledge about health services, health disparities, and the theory and methods of conducting community-partnered research.
- Increase participation of trainees in events by 25%, such as the CTSI K/Career Development Award Workshops, CTSI/RCMAR CHIME/Project EXPORT Scientific Retreats and monthly Methodological Seminars, and encourage them to present their work and/or submit writing drafts for review.

**Goal 3:** Continue to recruit the most qualified faculty as mentors for trainees and fostering interactions between fellows and faculty.
- Increase the number of health services and health policy researchers to serve as mentors for the TL1 trainees and develop a multidisciplinary team of 4 or 5 leading faculty and/or community members for each dissertation committee.
- Continue to require that the TL1 scholars present their work in progress to the CREST committee where they will have the opportunity to hone their presentation skills and obtain actionable feedback from leading scientists who conduct research that spans the translational science spectrum from bench to communities.
a. PERSONNEL

Leader: Pamela Davidson, PhD
Co-Leaders: Mohsen Bazargan, PhD; Lourdes Guererro, EdD; Moira Inkelas, PhD, MPH; Gerald Kominski, PhD; Deborah Koniak-Griffin, RN, EdD; Loren Miller, MD, MPH; Jack Needleman, PhD; Michael Weisman, MD; Alisa Wilson, PhD

b. STRATEGIC GOALS OF THE PROGRAM

Goal 1: Longitudinally track and evaluate initiative and program outcomes.

Goal 2: Implement a Performance Measurement and Improvement Initiative (PMII) with the intent of increasing efficiency, stimulating innovation and improving operational effectiveness in the CTSI and its research centers.

Goal 3: Create a transdisciplinary center for evaluation research to accelerate the speed and efficiency of translational research for improving organizational effectiveness and population health.

Goal 4: Collaborate with local, regional and CTSA national consortia and participate in national process and outcome evaluations.

c. PROGRAM CHARACTERISTICS

c.1. Process

The Evaluation Program is led by Dr. Davidson (40% effort), who is responsible for oversight of all Evaluation aims, serves on the CTSA Evaluation KFC, CTSI Operations, and CTRC Scientific Advisory committees. Four faculty represent partner institutions: Dr. Bazargan (4% effort) from Charles Drew University, Dr. Miller (4.5% effort) from Harbor-LA Biomed, and Dr. Weisman (2.5% effort) and Dr. Wilson (10% effort) from Cedars Sinai. Evaluation co-leaders at UCLA Westwood are Drs. Lourdes Guerrero (89% effort), Deborah Koniak-Griffin (5% effort), Moira Inkelas (5% effort), Gerald Kominski (2.5% effort), and Jack Needleman (5% effort). Research staff members Nicole Makowka, Jim Morrison, Terry Nakazono, and Jordan McCrary collect qualitative and quantitative data to monitor and evaluate the five CTSI goals.

c.2. Progress

In year 3 Evaluation emphasized high impact program accomplishments within each goal to build and strengthen the UCLA CTSI infrastructure and operations. These achievement stories are discussed in the sections below under each program goal: Goals 1-2: UCLA CTSI executive dashboard and performance measurement and improvement initiative, Goal 3: consultations to develop evaluation designs for extramural applications to promote standardized evaluation measurement and metrics in the research enterprise, and Goal 4: harmonize and standardize with the UC BRAID and National CTSA common metrics and priorities.

d. MAJOR ACCOMPLISHMENTS BY PROGRAM GOAL

Goal 1: Longitudinally track and evaluate initiative and program outcomes.

In 2012-13 and continuing in 2014, we launched the UCLA CTSI Executive Dashboard & Performance Improvement Initiative. In year 3 we collaborated with institute and program leaders to select metrics for the first dashboard organized around the five CTSI goals. Figure 1 shows the six major activities. Activities 1-3 were completed in year 3. Output and outcome metrics for the Executive Dashboard are reported in the Self-Evaluation (Table 1), found elsewhere in this document.

Goal 2: Implement a Performance Measurement and Improvement Initiative (PMII) with the intent of increasing efficiency, stimulating innovation and improving operational effectiveness in the CTSI and its research centers.

Figure 1 shows Activities 4-6 in the PMII that will be implemented in year 4. Evaluation will meet with CTSI leaders whose programs are directly linked to the Executive Dashboard metrics to propose a year 4 performance target, signal, and response that will be monitored and reviewed periodically (PMII #4). Additionally, the CTSI has contracted with AMC Consultants to develop a strategic plan for the CTSA competitive renewal. Evaluation’s role will be to work with stakeholders to develop a metrics-based strategic...
Goal 3: Create a transdisciplinary center for evaluation research to accelerate the speed and efficiency of translational research for improving organizational effectiveness and population health.

Forty-one (41) consultations with CTSI investigators were entered in the Team Science System (TSS) in year 3. Some of these involved preparing an evaluation design for extramural grant proposals. Our strategy is to apply standardized measurement tools for data collection, analysis, and reporting in research organizations in CTSI partner sites to ensure quality, effectiveness and efficiency in the research enterprise. In year 3, three multiyear CTSI-Evaluation projects were funded, as follows: (1) UC Center for Accelerated Innovation (CAI), UC BRAID campuses were awarded $12 million from the National Heart, Lung and Blood Institute (NHLBI) to establish one of three nationwide Centers for Accelerated Innovation. Evaluation will support the Director in conducting annual reports of Center progress; (2) 21st Century Dental Homes Project/Children's Dental Care Program (First5Los Angeles, Crall, PI; Davidson, Evaluation: 5 years/$20M; (3) Innovative tools for evaluating interprofessional competencies (J. Macy Foundation, Lyder, PI; Davidson, Co-PI, Guerrero, Evaluation: 2013-2015/Total $584,370); and (4) Community Health and Advocacy Training in Pediatric Dentistry (HRSA, Ramos-Gomez, PI; Davidson, Evaluation: 2013-2014/Total $494,000).

In terms of improving organizational effectiveness, CTSI-Evaluation has collaborated with several CTSI programs (e.g., BIP: develop the TSS and satisfaction surveys, Regulatory: identify standard metrics for tracking IRB/contracting metrics, CCRR: design/conduct a needs assessment for planning future services). Additionally we are participating in several UC BRAID and national CTSA initiatives (see Goal 4). In terms of measuring health impact and improving population health, access to dental care is one of the major public health challenges for low-income children from minority populations not only in Los Angeles County but throughout the nation. A primary objective of the Dental Homes Project/Children's Dental Care Program (Crall, PI), is to increase access to dental care for children ages 0-5 at highest risk for oral disease by establishing a dental home model in 22 community clinics over the next 5 years. CTSI-Evaluation is applying a quasi-experimental design to longitudinally assess the impact of the dental homes interventions and to compare access and oral health outcomes in the 22 clinics. In 2013, 9764 children 0-5 years visited the dentist in the 12 clinics; the five year project goal is to serve 53,000 additional children and to longitudinally track preventive services use and declines in oral disease.
Goal 4: Collaborate with local, regional and the CTSA National Consortia and participate in the national process and outcome evaluations.
Harmonizing common metrics in CTSAs regionally and nationally is critical for monitoring performance and comparative reporting to identify performance strengths and gaps. This allows evaluation to be more effective in uncovering barriers and implementing initiatives to accelerate the speed and efficiency of translational research. The Self-Evaluation section, found elsewhere in this APR, includes examples of outputs and outcomes we are measuring, e.g., UC BRAID “contracting” metrics. We have been involved in several UC BRAID and national CTSA initiatives in 2013: (1) UC Center for Accelerated Innovation (CAI), (2) UC BRAID Contracting Initiative, (3) UC BRAID Biobanking Workgroup, (4) UC BRAID/California Regional Evaluation Network, and (5) national CTSA Evaluation KFC Common Metrics Project.

e. OPPORTUNITIES AND CHALLENGES IN IMPLEMENTING RELEVANT PROGRAM ACTIVITIES

Our Executive Dashboard Initiative and the cross-component performance metrics linked to strategies in the strategic framework were cited as strengths by the External Advisory Board (EAB). We have proposed activities/timeline for responding to the year 3 EAB recommendations, as follows: (1) Digital Dashboarding Tool: we are collaborating with BIP to select software/IT platform for the dashboard that will include a web-based application to enable periodic reporting by partner sites; (2) Cost-Outcome Evaluation: in consultation with CTSI leaders we will select one or more high-priority cost analysis projects to build capability for optimizing profit and impact, cost reduction, resource allocation, and overall sustainability; (3) Tracking Career Outcomes: we are utilizing the RU GTSS tracking system along with other CTSAs. EAB suggested ORCHID ID -- currently under consideration by Evaluation and Education; (5) KL2 Education and Training Dashboard: Dr. Guerrero will collaborate with Education to propose and implement a dashboard; (6) IRB Process Mapping and Outputs: we are collaborating with Regulatory to track IRB metrics and will support measurement in future performance improvement initiatives.

f. MODIFICATIONS MADE TO ORIGINAL PLAN, ACTIVITIES OR FOCUS WITH RATIONALE

We modified our Goal 2 terminology, “Improvement Science Program,” to align with the Executive Dashboard initiative and the emerging Performance Measurement and Improvement Initiative (PMII), discussed above.

g. PLANS FOR COMING YEAR BY GOAL

Goal 1: Longitudinally track and evaluate initiative and program outcomes.
In 2014 when the new strategic plan is formulated, a second tier of output and outcome metrics will be selected that align with the executive dashboard initiative but also capture the evolving structure and strategic framework in the competitive renewal.

Goal 2: Implement a Performance Measurement and Improvement Initiative (PMII) with the intent of increasing efficiency, stimulating innovation and improving operational effectiveness in the CTSI and its research centers.
CTSI leaders will propose year 4 performance targets and high priority performance improvement projects that we will monitor and review periodically (see PMII section above). For example, we are working with the Regulatory Program to track IRB metrics and to identify bottlenecks to improve performance and the UC BRAID Contracting Directors to measure contracting processes.

Goal 3: Create a transdisciplinary center for evaluation research.
In 2014 we will continue consultations and will participate in submitting at least four extramural applications with an evaluation design (output) and anticipate at least one new funded evaluation design (outcome).

Goal 4: Collaborate with local, regional and the CTSA National Consortia.