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; Loretta Jones, MA
Key personnel: Bowen Chung, MD, MSPH; Eric Daar, MD; Susan Ettner, PhD; 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; Hector Rodriguez, PhD; Roberto Vargas, MD, MPH; Ronald Victor, MD; Michael Weisman, MD; Neil Wenger, MD; Mitchell Wong, MD, PhD; Aziza Wright, MA; David Zingmond, MD, PhD

b. Strategic Goals of the Program

Goal 1: Promote and sustain bidirectional knowledge-sharing between 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

c.1. Process

Drs. Brown (30% effort), Norris (10%), Shapiro (10%), Andersen (10%), Castro (5%), 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) and, in conjunction with Biostatistics Program, a programmer analyst.

c.2. Progress

We emphasized projects (Table 1) and leveraging CERP resources (Table 2) to strengthen the infrastructure and capacity for community-partnered, high impact, multidisciplinary translational research. We received 23 proposals in response to an RFA for community-partnered translational research and funded nine (total, $335,000; range, $18,000–$50,000), starting in September 2012. Academic and community awardees reviewed progress and lessons learned and discussed next steps at a learning network in December 2012.

Table 1. Progress on CERP projects awarded in year 2

<table>
<thead>
<tr>
<th>Project</th>
<th>Objectives</th>
<th>Products/Progress through 10/2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy Community Neighborhood Initiative (HCNI; formerly 70-block project)</td>
<td>Household interview, clinical exam, biomarker data collection, community asset mapping and neighborhood observations to inform recruitment and disease-reduction interventions.</td>
<td>• 63 household surveys completed&lt;br&gt;• 5 CHW and 6 grad students trained&lt;br&gt;• Community resource guide given out at free clinic event (5000 attendees)&lt;br&gt;• 3 scientific abstracts accepted&lt;br&gt;• Intramural funding</td>
</tr>
<tr>
<td>Magnolia Place Community Initiative (MPCI)</td>
<td>Identify scalable application of mobile health technology to improve community health.</td>
<td>• Smartphone data collection&lt;br&gt;• MPCI research infrastructure needs</td>
</tr>
<tr>
<td>Retaining Former Prisoners in HIV Care</td>
<td>Understand needs and resources of post-incarcerated HIV-positive clients.</td>
<td>• High rates of clinical &amp; social need&lt;br&gt;• Focus groups ongoing (7 planned)</td>
</tr>
<tr>
<td>Infrastructure to Increase Partnered Research with WIC</td>
<td>Establish research priorities and build research infrastructure within two WIC-CTSI partnerships.</td>
<td>• Developed questionnaire and conducted 10 focus groups</td>
</tr>
<tr>
<td>Enhancing Research in Communities of Color with Community Health Workers</td>
<td>Understand best practices for CHWs (promotoras) in research and develop a toolkit about working with CHWs for investigators.</td>
<td>• 3 focus groups with CHWs&lt;br&gt;• 7 interviews with community agency leaders</td>
</tr>
</tbody>
</table>
| CBPR to Enhance Recruitment of Minority Elders | Protocols for recruiting and retaining older adults in studies that involve biomarker | • Stakeholder interviews<br>• Review existing community-
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>L.A. Stroke Prevention/Intervention Research Program (SPIRP), Vickrey</td>
<td>NINDS</td>
<td>09/12-08/17</td>
<td>$11.1</td>
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<tr>
<td>Bridging Research, Innovation, Training &amp; Education (BRITE), Mays</td>
<td>NIMHD</td>
<td>08/12-01/17</td>
<td>$6.4</td>
</tr>
<tr>
<td>CDU/UCLA Project EXPORT Center, Norris/Shapiro</td>
<td>NIMHD</td>
<td>09/12–06/17</td>
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</tr>
<tr>
<td>Community Transformation Grant, Galloway-Gilliam</td>
<td>CDC</td>
<td>09/12–09/14</td>
<td>$3.5</td>
</tr>
<tr>
<td>The Center for Health Improvement of Minority Elderly (CHIME), Mangione</td>
<td>NIA</td>
<td>09/12–06/17</td>
<td>$2.8</td>
</tr>
<tr>
<td>Long-Term Outcomes Of Community Engagement To Address Depression Outcomes Disparities, Wells</td>
<td>PCORI</td>
<td>01/13-01/16</td>
<td>$2.06</td>
</tr>
<tr>
<td>Engaging UC Stakeholders for Biorepository Research (EngageUC), Johnston</td>
<td>NCATS</td>
<td>09/12–06/15</td>
<td>$2</td>
</tr>
<tr>
<td>Disseminating Community Partners in Care, Chung</td>
<td>CCF</td>
<td>07/12-06/14</td>
<td>$0.5</td>
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<td>CCF</td>
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CCF= California Community Foundation

d. Opportunities and Challenges in Implementing Relevant Program Activities

CERP infrastructure helped obtain $33.4 million in new funding for community-engaged research (Table 2). An important challenge within CERP has been trying to advance CERP/HSR goals in four institutions with heterogeneous experiences and infrastructure. Toward this end, we built infrastructure at Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (LA Biomed) with projects that allowed research staff to teach and learn in community settings. Clinical research staff helped to train lay health workers and community-based clinical staff in the development and execution of clinical research protocols. In turn, the research staff gained skills in community engagement and participatory research.

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

In addition to the modifications described in c.2, we have made the following changes in response to EAB recommendations:

- **Increase Latino representation.** We have recruited Dr. Daniel Castro, Chair of Family Medicine at Harbor-UCLA Medical Center, to the CERP leadership team. In addition, four of our nine projects have substantial representation from the Latino community.

- **Enhance sustainability of CERP.** Each CERP project and all working groups have been asked to submit a sustainability plan. We are working with the Anderson School of Management to develop measurements of social return on investment and strategies for enhancing sustainability.

We removed two activities from Goal 2 in year 2 because they were not feasible with the current resources: (1) Establish two community centers to support community engagement and research, and (2) Pilot test community health education and translational research centers (CC-HEATRs). We eliminated Goal 5 because it called for establishing an operating and governance structure, which we have achieved.

f. Major Accomplishments by Strategic Goal of the CERP Program

**Goal 1: Promote and sustain bidirectional knowledge-sharing between community and academia.**

- **Technical Assistance and Training for Health Disparities Research in East L.A.**
  - Objectives: Select, train, and employ community lay interviewers for a community intervention focused on healthy eating.
  - Products/Progress through 10/2012:
    - Developed a five-module training
    - Completed 300 community surveys

- **Behavioral Economics to Improve Safety Net HTN Control**
  - Objectives: A randomized trial of behavioral economics to improve blood pressure control in minority patients.
  - Products/Progress through 10/2012:
    - Completed study enrollment (N=207)
    - Manuscript in press, *JGIM.*

- **Collaborative to Reduce the Burden of CHF & CVD in South LA**
  - Objectives: Provide data on excess rates of CHF- and CVD-related hospitalizations and mortality and develop a disease registry to support evidence-based interventions.
  - Products/Progress through 10/2012:
    - Held three community stakeholder meetings to share CHF data

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CERP has used data collected from five symposia (1017 attendees), three seminars (109 attendees), two workshops (57 attendees), three health fairs (5000-25,000 attendees), 31 community partner surveys and 800 faculty surveys to determine leading community priorities (obesity/metabolic disease, homelessness, access to care) and investigator research needs (training in study design and analytic approaches for community-based research). CERP has provided consultations to 26 researchers (70% for assistance with research proposals) and 21 community partners (33% to assist with analysis, presentations, or proposals).

**Goal 2: Strengthen community infrastructure for sustainable, partnered research.** In addition the projects described under section c.2, CERP has three projects with the Los Angeles County public health system. First, we will issue in January an RFA with the Department of Health Services (DHS) for projects to improve productivity and value without increasing costs. We expect to fund 2–3 projects of $30,000 each. See section g below for details on the two other projects.

**Goal 3: Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.** We have partnered with the University of Minnesota on an RFA for community-engaged research on disparities and health system change. We have received eight proposals and will announce up to three awards of at least $50,000 each on December 20, 2012. We have drafted processes to facilitate dissemination and sustainability strategies for the Community Faculty Track at CDU.

**Goal 4: Build health services research (HSR) methods into partnerships to accelerate design, production and wide adoption of evidence-based practice and behavior.** The HSR team has formed a data analysis working group to identify and assemble data on disease burden within LA County (e.g. chronic disease “hotspots” and preventable admissions) and resources to address health needs. Data on CVD patterns in South LA were shared with local stakeholders who subsequently incorporated the findings into an NIH proposal (NIMHD R24 on CBPR to reduce health disparities). The three-year, planning-and-intervention-development proposal was favorably reviewed and is awaiting a funding decision.

**g. CTSA Consortium, Activities and Contributions**

- CERP collaborates with the USC CTSI and the county Department of Mental Health on the Mental Health Fellows Program.
- Faculty from CERP and the USC CTSI are co-investigators on a Department of Public Health proposal to develop rapid health impact assessments of education policies related to truancy and transportation. The brief proposal was favorably reviewed by the Robert Wood Johnson Foundation; the full proposal is in preparation.
- Presentations at the CTSA KFC (August, 2012; three poster presentations) and the NIMHD Disparities Summit (scheduled for December 2012; 17 UCLA CTSI presentations accepted).
- CERP will co-lead community participation in EngageUC, a UC-wide project to develop an ethical, efficient, and sustainable system for obtaining, processing, and sharing biospecimens and data.

**h. Plans for Coming Year**

**Goal 1: Promote and sustain bidirectional knowledge-sharing between community and academia.** CERP will establish, track and evaluate a formal Consultation Service to connect investigators and community partners, provide advice on study design and methodological questions, and offer training in community-based and health services research.

**Goal 2: Strengthen community infrastructure for sustainable, partnered research.** As noted above, we will fund several projects with LA County, including a practice-based research network (PBRN) to conduct adaptive clinical trials and quality improvement at Harbor/LA-Biomed and the DHS Ambulatory Care Network.

**Goal 3: Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.** CERP will conduct ongoing review of the products and impact of all projects and select projects for continued year 3 funding that have a high likelihood of successfully leveraging the additional funding to obtain extramural support.

**Goal 4: Build health services research (HSR) methods into partnerships to accelerate design, production and wide adoption of evidence-based practice and behavior.** The HSR “hot spot” analysis will provide reliable data to community partners and investigators on chronic disease patterns and health services at different levels of geography in LA County. These data will support proposals for funding, policy initiatives, and can be linked to other data sources, such as the Bioinformatics Program’s LA Data Repository (LADR).
a. Leadership

Leaders: David Martins, MD, MS; Leslie Raffel, MD, MS; Isidro Salusky, MD; Christina Wang, MD
Co-leaders: W. David Hardy, MD; Eli Ipp, MD; Michael Irwin, MD; Carl Maida, PhD; Ronald Mitsuyasu, MD
Key personnel: Linda Burns-Bolton, DrPH, RN; Loretta Jones, MA; Eric Kleerup, MD; Siegfried Rotmensch, MD; Lynne Smith, MD

b. Strategic Goals of the 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 Center for Health Sciences (CHS), Los Angeles Biomedical Institute at Harbor-UCLA Medical Center, Charles Drew University of Medicine and Science, and Cedars-Sinai Medical Center. Inpatient facilities are located at CHS and Harbor-UCLA/LABIomed. Program leaders have the following levels of effort: Dr. Martins, 15%; Dr. Raffel, 25%; Dr. Salusky, 20%; Dr. Wang, 30%. CTRC staff includes experienced research nurses, research dieticians, phlebotomists, clinical research coordinators, clinical nursing assistants, and recruitment specialists. Facilities available to aid investigators include sample processing labs, two metabolic kitchens, two DEXA scanners for measurement of body composition, and two sleep study facilities.

c.2. Progress

During our second year, we continued to focus on maximizing coordination among the four CTRC sites with—as recommended by the External Advisory Board (EAB)—the goal of increasing “utilization of resources across the four partnering organizations.” CTRC leadership meets monthly by videoconference to discuss ways to improve coordination and a major focus has been development of CCRR-wide processes and procedures. We continue to improve the common CTRC service application form. Because two of the four sites have CTRC service requests and scientific advisory committee review procedures that are integrated into their IRB application process, CCRR leadership has determined that the focus should be on assuring that the information collected in each partner institution’s CTRC application is the same. At present there is no plan to designate the use of a specific computer program/platform to submit applications across all institutions. We also are working on a supplementary application form that will enable investigators to request services at partner locations without repetition of data from the primary CTRC application; we hope this will serve to encourage investigators to consider using resources at multiple sites. Another key focus has been on developing our cost-sharing procedures and the tracking capabilities that are necessary to manage cost-sharing efficiently. With the knowledge that several tracking systems within the national CTSA consortium are being developed, we have opted to start with an interim, internally developed tracking system that is linkable to WebCAMP. When a program that meets the UCLA CTSI’s needs becomes available, we hope to perform ß-testing for local use. Dr. Salusky serves as the point person for the CTSA Child Health program (CC-CHOC), participates in its regular conference calls and distributes listings of potential clinical trials to each CTSI site.

The initial standard operating procedures (SOPs) drafted by CTRC research nurses and dieticians has been implemented across all sites. This standardization began in year 1 with the most commonly requested procedures and has been very effective. CTRC nursing staff now routinely add new SOPs whenever investigators request a test or procedure for which a SOP does not exist, so the number of SOPs is growing.

The Regulatory Program has successfully implemented a CTSI-wide IRB Reliance-Review Model for multisite studies. The model allows investigators wishing to perform research at more than one CTSI site to submit a single IRB application to their home institution, which serves as the Reviewing IRB and the IRB of Record,
minimizing duplicative IRB review. While investigators who have used this process have found it very effective, there have been fewer requests than anticipated. From Jan.–Oct. 2012, the Reliance-Review IRB received, reviewed and approved a total of 12 protocols. CCRR is working with the Regulatory Program leadership, the IRBs and the research facilitators within the Office of Investigator Services to develop ways to increase awareness of the Reliance Review process, as we believe that there is much more collaborative research across our institutions that could benefit from this process.

Several programs bridging across Community Engagement in Research Program (CERP) and CCRR are in development. CCRR nurses and bionutritionists have provided training on research procedures for the Healthy Community Neighborhood Initiative (formerly 70-block project) and are assisting a K23 awardee with his HIV prophylaxis pilot project, which is located in two community clinics. CCRR is supporting another very exciting project on HIV prophylaxis which involves our four CTSI institutions, UCSD, USC, the Los Angeles County Office of AIDS and community partners. CCRR is also providing assistance to two NIDA-funded, early phase clinical trials related to methamphetamine abuse, both of which involve the departments of Family Medicine (UCLA) and Psychiatry (Harbor-UCLA/LA BioMed), along with community clinics. In the second half of 2012, CCRR initiated discussions with the Weingart YMCA in South Los Angeles to establish a Lifestyle Intervention and Food Education (LIFE) Center on its premises. The LIFE Center would draw on the CTRC resources of our four CTSI partner institutions and serve as a community hub for translational research endeavors around obesity and its associated morbidities. The LIFE Center, if successful, could serve as a model Community Center in Health Education and Translational Research (CC-HEATER), a community-based research unit that also serves as a repository of clinical trial and health information of interest to the community in which it is located.

The CTRC’s continue to provide support for our many clinical and translational investigators. In 2012, 306 existing research projects continued to be performed and 119 new protocols were initiated, for a total of 8137 outpatient visits and 744 inpatient stays. The figures include actual data for the first 10 months and annualized data for November and December. While higher than in our first year, comparisons to 2011 are not meaningful because prior-year operations in Westwood were negatively impacted by a move into newly renovated space.

c.3. Opportunities in Implementing Relevant Program Activities

We need to expand our involvement in more community-based projects and this requires increased awareness of what CCRR offers. To this end, CCRR staff will be participating in the half-day CERP “Learning Network” meeting scheduled for December 4, 2012. This meeting will include investigators, community participants and leaders of successful community-based projects speaking on their experiences with community collaborative research. CCRR will be available to discuss the research support needs that attendees may require and assist with requesting such support.

c.4. Challenges in Implementing Relevant Program Activities

Our experience with the IRB Reliance-Review process has clearly indicated that developing a more efficient process may not be enough to result in the adoption of that process. Better ways to publicize the CTSI and its innovations are necessary. In the case of IRB Reliance, CCRR is working with the Regulatory Program leadership, the IRBs and the research facilitators to develop ways to increase awareness of the Reliance-Review process, as we are quite sure there is much more collaborative research across our institutions that could benefit from this process. Another challenge is the impact the current fiscal environment has for implementing cost-sharing. While we appreciate the EAB's perspective that aggressive cost-sharing is needed to prepare for future reductions in NIH support for CCRR activities, many faculty, especially those just beginning their academic careers, find it difficult to identify the financial resources needed to cover cost-sharing dollars. To minimize this negative effect, waiver of cost-sharing and/or reduced cost-sharing rates are being made available to new investigators.

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

While we recognize the critical importance of transitioning to an investigator cost-sharing model for CCRR services, in the current challenging fiscal climate, we also recognize that cost sharing may be very difficult for some investigators, particularly young investigators who do not have alternative resources available to them. Thus, we are modifying our cost-sharing programs to include additional support to young faculty and are
increasing the percentage of cost-sharing gradually, so that investigators have time to identify alternate sources of funding. Different models are currently being evaluated.

e. Major Accomplishments by Goal

Goal 1: To broaden the scope and efficiency of clinical, translational and community research by implementing the CCRR without walls. The restructuring of the CTRCs and their staffs has succeeded in shifting the focus to outpatient research activities while still offering support to those investigators whose research requires inpatient services. Outreach activities are growing gradually as are cross-institutional collaborations.

Goal 2: To promote collaborations across the CTSI partner institutions. The standardization of clinical research SOPs and implementation of the IRB Reliance-Review Model are serving to make cross-institutional collaboration simpler and more straightforward. We continue development of a common CCRR application form to facilitate cross-CTSI service requests, along with a program for cost-sharing calculation and tracking. With the aid of the Office of Investigator Services and its research facilitation program, we are increasing publicity about CCRR resource availability and also efforts to connect investigators with complementary research interests across the CTSI.

Goal 3: To recruit junior professionals into careers in translational clinical research. The CCRR leadership meets regularly with junior faculty to provide guidance on translational clinical research. We actively participate in a variety of educational activities, including the Training Program in Translational Science (graduate level), the Pathway on Clinical and Translational Medicine (medical students) and the Long Beach Polytechnic program (high school) and with the assistance of the CTSI Research Education, Training and Career Development Program (CTSI-ED), we are exploring options for expanding the existing program to other high schools. In addition, we are organizing a combined course covering grant writing and clinical trial development to be led by Cedars-Sinai and UCLA and open to faculty and trainees at all partner institutions. We are encouraged that three medical students enrolled in the Pathway on Clinical and Translational Medicine have expressed interest in taking a year off to continue their research endeavors.

f. CTSA Consortium Activities and Contributions: Members of the CCRR leadership participate in several of the CTSA KFCs, including the Clinical Research Management, Clinical Service Core, Community Engagement, and Regulatory KFCs. They participate in the KFC and CTSA Child Health Program conference calls regularly and have attended the annual national Clinical Research Management meeting.

g. Plans for Coming Year

Goal 1: To broaden the scope and efficiency of clinical, translational and community research by implementing the CCRR without walls. During the coming year, we will continue to interact with the CERP program and our community partners, offering support for clinical research activities. We anticipate implementing the LIFE Center at the Weingart YMCA in South Los Angeles, which will serve as a means (and example) of testing the feasibility of performing clinical research activities outside of the traditional hospital/clinic setting. We also expect to implement a collaborative psychiatric research program between UCLA and Mission Community Hospital in the San Fernando Valley.

Goal 2: To promote collaborations across the CTSI partner institutions. We will organize meetings with investigators with common research interests across the partner institutions to identify collaborative projects that can be performed with the assistance of the CTRCs. By joining forces in this way, we hope to increase collaboration, facilitate the rapid collection of preliminary data for new projects and encourage submission of grant applications for extramural funding. The facilitators in the Office of Investigator Services will aid in identifying investigators with complementary interests across the partner institutions, whose research could benefit from CCRR resources. We will work with the Regulatory Program to generate a minimum of 18 IRB Reliance-Review applications in 2013, a 50% increase over 2012.

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 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. Leadership

Leaders: Robert M. Elashoff, PhD; Steven Piantadosi, MD, PhD; David Elashoff, PhD; Andre Rogatko, PhD
Co-leaders: Teresa Seeman, PhD; Magda Shaheen, MD, PhD; Peter Christenson, PhD; Roger Lewis, MD, PhD
Key personnel: Thomas Belin, PhD; Catherine Crespi, PhD; David Gjertson, PhD; Xiulong Guo, PhD; Steve Hovarth, PhD, ScD; Gang Li, PhD; Xiaoyan Wang, PhD; Heijing Wang, MD, MPH; Li-Jung Liang PhD, Chi-Hong Tseng, PhD

b. Strategic Goals of the 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 the unique requirements of community-based research.
Goal 3: Provide biostatistical education and training.

c. Program Characteristics

c.1. Process

Leadership: BCB 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 2, 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.

Staffing: In year 1, to fill the biostatistical needs of the CTSI, we hired two fulltime master’s degree statisticians (Grogan and Anene) and allocated funds to partially support three additional PhD statisticians at 10–40% effort. In year 2, an additional master’s degree statistician was hired (Sitaram Vangala). Mr. Vangala has taken on biostatistical consulting responsibilities for projects arising in the Community Engagement in Research Program (CERP) under the direction of Drs. Liang and Elashoff. His position is 50% effort for supporting CERP projects and 50% for supporting general CTSI projects. Additionally, to provide collaborative support for the new computational biology initiative, we have brought on two additional faculty: Dr. Thomas Graeber (10%), a specialist in developing genome-, proteome- and metabolome-wide assays and developing computational approaches aimed at overlaying raw molecular data with known signaling- and metabolic-network structures; and Dr. Xiaoyan Wang (20%), an expert in statistical analysis of high-throughput molecular data with experience with microarray and next-generation sequencing analysis. Finally, two part-time (50% effort) staff level computational biologists/statisticians will be hired to support the collaborative efforts of the new faculty personnel in the program. BCB 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 BCB to provide an enhanced level of service to collaborations.

Service Prioritization: BCB 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 have begun utilizing a new team science workflow management system that provides a common platform and database for logging effort on collaborative projects, coordinating between multiple BCB faculty
and staff working on those projects, communicating with collaborators, and triaging projects to those faculty and staff in the program with appropriate expertise.

c.2. Progress

**Statistical Consulting:** Exclusive of administration and special courses, the total statistical consulting hours with investigators at the four institutions was 9,372.5 for the period Jan. 1, 2012 to Nov. 1, 2012. This was broken down as follows: 4,474.2 hours for data analysis; 824.9 hours for study design; 1,763.4 hours in grant preparation assistance, 855 for statistical methodology research on consulting projects, 268 hours for statistical education and 1,155 hours in data management. We have collaborated on 728 projects. The overall level of support was comparable to year 1, although in year 2 faculty time was lower and staff time was higher. Our consultations resulted in the submission of 26 manuscripts in that period. We assisted 367 unique investigators on 580 projects. Of all collaborators, 6% were medical students and graduate students; 25.1%, residents and fellows, 32.4%, assistant professors and instructors; and 36.4%, associate and full professors. Additionally, the program is piloting a new drop-in statistical consulting service at UCLA. Based on an EAB recommendation, we have included biostatistics/computational biology consulting services for those who receive CTT genomics vouchers. This will ensure that genomics data produced by these vouchers be analyzed.

**Educational Activities:** BCB statisticians lectured on introductory statistics at all four partner institutions and conducted a grant writing workshop for pediatric fellows. BCB faculty members participated as grant reviewers and discussants at the inaugural CTSI K-Award workshop and will participate in subsequent workshops (see Research Education, Training and Career Development Program report). The workshop led to three new collaborations with junior faculty working on developing K-award applications. Nine new students enrolled in the Master's in Clinical Research (MSCR) program, bringing total enrollment to 23, the same as in 2011.

c.3. Opportunities and Challenges in Implementing Relevant Program Activities

A key challenge for the program, as noted in the EAB report, is how to expand the pool of available biostatisticians as demand for services increases. One solution is to develop more collaborations like the one we have with the Department of Pediatrics, in which that department supports additional BCB program faculty in return for greater access to statistical support. This approach increases the size and diversity of the BCB consulting team, thus enhancing the overall program. We are discussing this approach with a second department.

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

A substantial modification to the program is the addition of computational biology and bioinformatics consulting with the addition of funding for 30% FTE of faculty time and 100% FTE of staff time. These improvements were motivated by the explosion of high-throughput molecular studies. These studies require support with study design, sample size estimation and experimental procedures. Once data are generated there is a substantial unmet need for assistance with the analysis of that data. To address this need, we added additional faculty and staff as described above. This has resulted in modifying program goals 1 and 3 and changing the name of the program to reflect the new focus.

e. Major Accomplishments by Goal

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

With the addition of Dr. Liang and the hiring of Sitaram Vangala we have significantly enhanced statistical consulting and CDM services to community studies, providing 1,000 hours of assistance for data analysis, study design, and data management. BCB leader Dr. R. Elashoff and Dr. Ronald Victor of Cedars-Sinai Medical Center successfully collaborated to receive a $443,226 award to plan a Duchene’s muscular dystrophy trial. (U34 AR062893)

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

One accomplishment of the program is research into for high throughput gene co-expression network data analytic techniques. Co-expression measures are often used to define networks among genes. Mutual information (MI) is often used as a generalized correlation measure. This research provides a comprehensive empirical comparison between mutual information and several correlation measures in eight empirical data
sets and in simulations. We also study different approaches for transforming an adjacency matrix, e.g., using the topological overlap measure. Overall, we confirm close relationships between MI and correlation in all data sets which reflects the fact that most gene pairs satisfy linear relationships. We show that a robust measure of correlation (the biweight midcorrelation transformed via the topological overlap transformation) leads to modules that are superior to MI based modules in terms of gene ontology enrichment. The biweight midcorrelation outperforms MI in terms of elucidating gene pairwise relationships. Coupled with the topological overlap matrix transformation, it often leads to more significantly enriched co-expression modules. Our results, which BMC Bioinformatics has accepted for publication, indicate that MI networks can safely be replaced by correlation networks when it comes to measuring co-expression relationships in stationary data.

We have also instituted a Biostatistics-CERP program joint seminar series and methodology working group. The aim of this working group and seminar series is to cross-pollinate the two fields, bringing novel statistical methods and statistical education to community researchers as well as to identify specific areas of community study research methodology that require biostatistical methods development. This seminar series began in October 2012 with a well-attended and well-received seminar by Dr. Belin, who described the application of a community-participatory methodology for clinic randomization to a community-partnered research study.

**Goal 3: Provide biostatistical education and training.**

**Didactic courses:** We have expanded upon the course offerings in the UCLA Master’s in Clinical Research (MSCR) program by adding courses in grant writing and high-throughput data analysis, including microarrays and next-generation sequencing data analysis. Through video-conferencing, we expanded availability of introductory statistics, regression analyses, and clinical trial and observational studies courses to Cedars and LA Biomed.

**Seminar:** We have developed a seminar about statistics sections in grant applications and delivered it to four audiences with a total of 90 attendees.

**f. CTSA Consortium Activities and Contributions**

Dr. D. Elashoff attended the Biostatistics, Epidemiology and Study Design (BERD) KFC meeting in April 2012 and participates in the BERD teleconferences. The program had collaborations with the Universities of Florida, Pennsylvania, Iowa and UC Davis on development of the clinical trials designed with Dr. Victor. Additionally, Dr. D. Elashoff and Dr. Steve Dubinett have extensive collaborations with Boston University and Vanderbilt University on lung cancer biomarker development and validation studies.

**g. Plans for Coming Year**

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

Besides continuing our current services, we will fully develop our new computational biology service through the planned hiring of two additional data analytic staff members. In collaboration with the Center for Translational Technologies, and in response to EAB recommendations, we will initiate vouchers for the use of the BCB consulting services for larger scale projects that are not currently supported by the program.

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

We plan to continue the Biostatistics CERP working group and seminars and plan to initiate a collaborative statistical method research project based on the identified needs of the CERP investigators. Based on the additional faculty in the computation biology area, we plan to develop a methodology for integration of multiple high throughput molecular data types.

**Goal 3: Provide biostatistical education and training.**

The program plans to continue to increase the availability of didactic and seminar-based biostatistical education at the partner institution through videoconferenced courses and through the use of the Moodle to place biostatistical lectures and course content in the hands of residents, fellows and junior faculty throughout the four institutions. 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. Leadership

Leaders: Stanley G. Korenman, MD
Co-leaders: Stuart Finder, PhD; Stewart Laidlaw, PhD; Eifaang Li, DVM, MPH; Catherine Mao, MD; Junko Nishitani, PhD; Laurie Shaker-Irwin, PhD, MS
Key personnel: Sharon K. Friend, MS; Brian Kan, MD, MS

b. Strategic Goals of the 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: Develop pre- and post-approval regulatory support services through deployment of an Office of Investigator Services and creation of a UCLA CTSI-wide “one-stop shop” for approval and oversight of CTSI-supported science.

Goal 3: Develop a Research Ethics Consortium and continuing education system for CTSI investigators and participants to enhance ethical sensitivity, understanding of regulations and good clinical practices, and mentoring and learning.

c. Program Characteristics

Process: Dr. Korenman (40% effort) directs all aspects of the Program. Dr. Laidlaw (5% effort) leads the continuing education program; Dr. Finder (5% effort) leads the ethics program; Dr. Li (5% effort) leads the Institutional Review Board (IRB) harmonization work; and Drs. Mao 30% time and Shaker-Irwin (100%) direct the Post-approval Research Oversight (PARO) program, which includes the Research Subject Advocate (RSA) program and includes Dr. Kan (45%); Dr. Shaker-Irwin also directs the Office of Investigator Services (OIS); Ms. Friend has 5% effort at no pay. Dr. Nishitani works 5% time. Dr. Raffel works 5% time in Ethics. Leaders work collaboratively in groups but are physically located at and supported by their home institutions.

Accomplishments

Goal 1: IRB Harmonization. Table 1 below presents IRB turnaround times for the nine months ending Sept. 30. (Numbers may not add due to rounding.) We will evaluate turnaround times on an ongoing basis in year 3.

Table 1. IRB turnaround times (in days) on new studies approved Jan. 1–Sept. 30, 2012

<table>
<thead>
<tr>
<th>Metric</th>
<th>Charles Drew</th>
<th>LA Biomed</th>
<th>Cedars-Sinai</th>
<th>UCLA Westwood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # of New Studies Approved</td>
<td>7</td>
<td>2</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>Average Turnaround Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>from Submission to 1st IRB Action</td>
<td>35</td>
<td>13</td>
<td>26</td>
<td>11</td>
</tr>
<tr>
<td>Average Turnaround Time from 1st IRB Action to IRB Approval</td>
<td>45</td>
<td>1</td>
<td>20</td>
<td>17</td>
</tr>
<tr>
<td>Average Turnaround Time from Submission to IRB Approval</td>
<td>80</td>
<td>14</td>
<td>46</td>
<td>28</td>
</tr>
</tbody>
</table>

In year 1, we instituted a Reliance IRB process for CTSI collaborative projects. This allows the IRB of one institution (Relying IRB) to rely on the IRB of another institution (Reviewing IRB) for review and continuing oversight of human participant research. A revised MOU documenting the reliance review process was executed March 26, 2012. We subsequently developed and finalized instructions, forms for protocol submission, and a review procedure. A total of 12 protocols were reviewed between November 19, 2011 and
October 31, 2012 (Table 2). A 0.5 FTE CTSI IRB analyst was assigned to this project in August 2012. We expect applications will increase as we step up our marketing efforts.

Table 2. Reviewing-Relying IRB protocols.

<table>
<thead>
<tr>
<th>Lead PI</th>
<th>Relying PI</th>
<th>Review/Rely IRB</th>
<th>Study Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steven Shoptaw</td>
<td>Nina Harawa</td>
<td>UCLA/CDU</td>
<td>Feasibility Study of a Community-Level, Multi-Component Intervention for Black Men Who Have Sex With Men (HPTN061)</td>
</tr>
<tr>
<td>Keith Norris</td>
<td>Arleen Brown</td>
<td>CDU/UCLA</td>
<td>Healthy Community Neighborhood Initiative: A Pilot Study within the 70 Block Project</td>
</tr>
<tr>
<td>Michael Ong</td>
<td>Bruce Davidson</td>
<td>UCLA/CSMC</td>
<td>Variations in Care: Comparing Heart Failure Care Transition Intervention Effects</td>
</tr>
<tr>
<td>Joshua Zaritsky</td>
<td>Kamyar Kalantar-Zadeh</td>
<td>UCLA/ LA Biomed</td>
<td>Hepcidin and Anemia of CKD</td>
</tr>
<tr>
<td>Rebekah H Child, Janet Mentes</td>
<td>Rebekah Child</td>
<td>UCLA/CSMC</td>
<td>Patient Safety, Coping, Social Support and Appraisal in Emergency Department RNs Who Have Experienced Workplace Violence</td>
</tr>
<tr>
<td>Lauren Patty</td>
<td>Eli Ipp</td>
<td>UCLA/LA Biomed</td>
<td>The impact of implementing a primary care-based tele-retinal screening protocol in the LAC safety net</td>
</tr>
<tr>
<td>David Miklowitz</td>
<td>Ira Lesser</td>
<td>UCLA/ LA Biomed</td>
<td>Early Family Intervention for Youth with Bipolar Disorder and Psychosis: Clinician Training and</td>
</tr>
<tr>
<td>James McKinnell</td>
<td>James McKinnell</td>
<td>UCLA/ LA Biomed</td>
<td>Identifying Modifiable Predictors of Treatment Success for Bloodstream Infections</td>
</tr>
<tr>
<td>Bowen Chung</td>
<td>Bowen Chung</td>
<td>UCLA/ LA Biomed</td>
<td>Building Resiliency And Community Hope</td>
</tr>
<tr>
<td>Walter Ling</td>
<td>Eric Daar</td>
<td>UCLA/ LA Biomed</td>
<td>Project HOPE – Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users</td>
</tr>
<tr>
<td>Eric Daar</td>
<td>Walter Ling</td>
<td>LA Biomed /UCLA</td>
<td>Project HOPE – Hospital Visit as Opportunity for Prevention and Engagement for HIV-Infected Drug Users</td>
</tr>
<tr>
<td>William Wilcox</td>
<td>Deborah Krakow</td>
<td>CSMC/UCLA</td>
<td>The Skeletal Dysplasia Registry – Genetics and the Pathogenesis of the Skeletal Dysplasia</td>
</tr>
</tbody>
</table>

In December 2012, the Assn. for the Accreditation of Human Research Protection Programs (AHRPP) awarded Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (LABiomed) full accreditation of its Human Research Protection Program.

Goal 2: Investigator services. OIS became fully functional with facilitators and post-approval research oversight (PARO) personnel recruited at each partner. We recruited 75 domain experts to assist investigators with biostatistics, study design, regulatory matters, and other specialized areas. OIS responded to 454 total requests during the first 10 months of 2012; 45% of queries came from e-mail and most resolved in an hour or less. OIS collaborated in the development of a novel online service request and tracking system that was deployed in November 2012. This is designed not only to help investigators, but to identify inefficiencies for amelioration. To promote its services and expertise, OIS held a workshop series at UCLA, which is being rolled out at our partner institutions. Our facilitators assisted with several successful grant applications, including a three-year, $9-million award from NIMH for a multi-site study to test translational therapeutics for autism (J. McCracken, PI); a $2-million administrative supplement from NCATS to advance a biobanking project among the five University of California medical campuses with CTSAs (S. Dubinett, Co-PI; S. Dry, Co-Director); a $6-million award from the California Institute for Regenerative Medicine to study a potential therapy for Duchene's muscular dystrophy (S. Nelson, PI); and a five-year, $1.4 million NIH award to study treatment of hospital-based staphylococcal septicemia in collaboration with Duke University (Z. Rubin).

Post-approval research oversight. PARO made progress in harmonization of procedures, especially data safety monitoring plans (DSMP) and review processes in anticipation of achieving review reliance. During the
reporting year, PARO personnel performed 50 DSMP consultations and 108 quality-assurance reviews. There were 56 incidents that required involvement of research subject advocates or the IRB.

**Goal 3: Research ethics and continuing education.** The multi-institutional ethics consultation program has been activated and six consultations have been given. A needs assessment process has been initiated to sensitize researchers to ethical issues and to determine the most fruitful approach to provide this service. The “Responsible Conduct of Research Involving Humans” course directed by Dr. Korenman has doubled its enrollment to 140. A complete inventory of responsible conduct of research and other relevant course given at each partner was completed and placed on the CTSI website. Each institution is mandated to provide instruction and certificate the students. All four partners use the CITI basic course in responsible conduct of research to certificate researchers for conducting clinical and translational research.

d. **Opportunities and Challenges in Implementing Relevant Program Activities**

Sharon Friend has spent considerable effort in developing and examining the Web-based reliance, registration and tracking application being used by University of California IRBs, including those at the five UC medical campuses with CTSAs. The plan is to examine the feasibility of adopting the UC model for the UCLA CTSI. While we don’t conduct a systematic review of all the elements involved in launching a new protocol, the facilitators are in a position to identify and assess impediments and delays and the IRBs and Contracts and Grants offices keep metrics that allow us to identify their degree of timeliness. The PARO system using the RSA cadre works regularly to make the post-approval process more efficient while assuring proper quality assurance. The CTSI ticketing system is set to identify efficiency issues that could use attention.

e. **Modifications Made to Original Plan, Activities or Focus, with Rationale.** CTSI Associate Director John Adams, MD leads our public-private partnership efforts, with support from the CTSI Office of the Institute (see Highlights, Milestones and Challenges). Consequently, the Regulatory Program no longer intends to support an Office of Industry Alliances, as described in our year 1 report. We have modified Goal 3 and no longer intend to centrally administer our continuing education and certification programs. The continuing education inventory indicated a substantial number of entries at each partner, very different times and offerings related to the various researcher populations and a functional certificating system. All of the partners use the basic CITI e-course to certify individuals for clinical and translational research participation. Thus, each fulfills its NIH and federal educational mandates. However, some educational offerings are being video-conferenced for CTSI-wide use including “Responsible Conduct of Research on Humans.” In response to budgetary pressure and to breakdown silos, Regulatory components at UCLA in year 3 will be situated within the administrative and CCRR budgets (see budget justification).

f. **CTSA Consortium Activities and Contributions**

Dr. Korenman works with the Regulatory KFC on conflicts of interest and the Ethics KFC on terms and conditions for consulting with commercial entities and in providing support to public-private partnerships. PARO leaders are active in the Regulatory KFC subcommittee on DSM, Recruitment and Retention, RSA, and Clinical Coordinator Training and Education. Dr. Finder is active in the Ethics KFC with regard to research ethics consultations. Sharon Friend is active in the UC-wide CTSA consortium regarding IRB harmonization. Dr. Mao attends the CC-CHOC quarterly meetings and its Pediatric Development Subcommittee.

g. **Plans for Coming Year**

**Goal 1: Harmonization.** Complete informatics database for the IRB Reliance-Review process and increase demand for service by marketing to potential investigators directly through the facilitator program and the PARO program. Our goal is to increase IRB Reliance-Review applications by 50%. Assess IRBShare, especially if a pilot currently being carried out at UCSF is successful. Collaborate with Community Engagement in Research Program to establish guidelines for community-based participatory research.

**Goal 2: Investigator Services.** Complete harmonization of PARO functions among the partners to include DSM, incident reporting, quality assurance and recruitment and retention and develop a review reliance mechanism to achieve greater efficiency through harmonization processes. Achieve full implementation of the ticketing system for all OIS services.

**Goal 3: Research Ethics and Continuing Education.** Conduct a needs assessment for ethics consultation. Actively promote ethics services to conduct more consultations by following up on the needs assessment. Continue to expand videoconferencing of individually developed courses and enhancing interactivity.
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 the Program

Goal 1: Advance transformative collaborative translational research through 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, 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 from Richard Baker, MD of Charles Drew University of Medicine and Science (CDU); David I. Meyer, PhD of Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (Harbor); and Leon Fine, MD of Cedars-Sinai Medical Center (Cedars). All leaders and co-leaders contribute 5% effort at zero salary.

Dion Baybridge, Director of Research, works with Dr. Rome to manage the finances of the program in close partnership with Matthew McPeck, the CTSI Financial Officer. Administrative assistance has been provided by Dr. Rome’s office and the CTSI. Dr. Rome’s effort as well as the effort of his staff has been provided by the DGSOM as part of the institutional contribution to the CTSI. Web support to the program comes from both the BIP and from Computer Technologies Research Laboratory (CTRL), a Web programming core facility that reports to Dr. Rome. The Director of CTRL, Dr. Robert Dennis is partially supported from the CTSI, however, 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

c.2.1. Opportunities and Challenges in Implementing Relevant Program Activities

The pilot program has a broad range of support vehicles that have been implemented over the first two years of the program. All of the grants 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. (Our second year results are summarized here; see pilot grant reports for details.)

We awarded 12 CTSI Scholars seed grants, supported nine UCLA/CDU Resource Centers for Minority Aging/Center for Health Improvement for Minority Elders (RCMAR/CHIME) scholars and three Los Angeles County Department of Mental Health Fellowships with USC. All CTSI Scholars are junior faculty at the Assistant Professor level. The CTSI Scholars Program is a seed grant program that provides mentored research in all areas of investigation.

To aid in the administration of this and all future CTSI pilot grant programs, last year we developed a Web-based online application, review and management software. This tool has allowed us to collect our second round of 24 new CTSI Scholar seed grant applications and is currently assisting in the assignment of reviewers, collection of reviews and applicant tracking. We are now assigning faculty whose reviews will be due in three months. 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 the Center for Translational Technologies also utilize this online tool to administer applications for their KL2 and voucher programs, respectively.

The **Team Science Awards (formerly Team Cluster Grant Program)** supports multidisciplinary team-based research. We successfully identified and leveraged nine Team Science Awards this past year which address issues in cardiovascular disease, cancer, AIDS, patient safety and dentistry. We are currently identifying additional institutional resources with the UCLA neuroscience community to sponsor a Team Science Award.

We developed the **Catalyst Grants** to create interaction 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 21 awards totaling $335,000 ($206,053 from CTSI support; $128,775 from institutional support) supported such activities as the Older Americans Independence Center (OAIC) rapid grants program, the RCMAR/CHIME retreat, Institute for Molecular Medicine seminar series, and the CTSI Maternal, Child, and Adolescent Health (MCAH) network.

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. In year 2, we awarded $200,000 to the Rapid Response Team (RRT) to improve its grant-preparation software, catalyze collaborations and develop its administrative infrastructure. RRT responds to Patient Centered Outcomes Research Institute (PCORI) initiatives and opportunities to assist investigators with the preparation and submission of proposals that have a submission window of two-months or less.

We awarded one **Prototype Grant** of $40,000 this past year to the UCLA Business of Science Center to support technology development teams composed of UCLA faculty inventors and UCLA Anderson School of Management MBA students. Three emerging technologies are now moving toward commercialization.

- **Xiao Hu, PhD: “Algorithm for Continuous Brain Assessment Using Intracranial Pressure.”** A team of Dr. Hu, two MBA students one PhD student from Dr. Hu’s lab is in the final stages of forming a startup to license and commercialize the technology.
- **Jason Schiffman, MD: “New Use of Drug for Psychosis and Bipolar Disorder.”** Dr. Schiffman has decided to license his technology to his own company to continue its commercial translation.
- **Majid Sarrafzadeh, PhD: “FunRehab—Mobile Rehabilitation Gaming System.”** A company has expressed interest in acquiring the technology.

We have delayed full implementation our Technology Transfer and Prototype Grant program, which is intended fund preclinical studies and phase I clinical trials. We expected funding for these programs to come from a broad-based partnership we had established with an industry partner. Because the company merged with another entity this partnership no longer exists. We are currently discussing new partnerships with a number of biotechnology companies and foundations and we anticipate that we will be able to fully institute Technology Transfer and Prototype grants in the near future.

### c.2.2. Modifications Made to Original Plan, Activities or Focus with Rationale

In June of 2012 our External Advisory Board (EAB) reviewed the Pilot Program and reported a number of strengths and assets focusing on the impressive number and variety of internal grant programs that we have instituted and the considerable amount of resources available both internal and external. The EAB also suggested that we might want to institute a continuous review of incoming requests rather than periodic (e.g., annual). We have considered this suggestion and decided to increase the frequency of review of our Catalyst Grant program to every four months. We are also considering whether it will be necessary to offer an incentive to internal reviewers, although thus far this has not been necessary as our faculty have been very good at complying with our review requests. Finally, we will include tech transfer (IP) progress and peer-reviewed publications in our measures of success of the pilot program.

### 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 113 pilot grants this year. These awards leveraged $2.3 million in direct CTSI and $2.45 million in institutional matching support. Of the
total, we partnered with UCLA centers and institutes to fund nine Team Science awards with $815,000 in CTSI support and $500,000 in institutional support. We have seen a return on investment of $18 million on our year 1 pilot awards of $1.8 million. This includes a five-year, $11.2-million award from NIDDK to year 1 pilot awardee Dr. Barbara Vickery to study a stroke prevention/intervention program in health disparities population and a $6-million award from the California Institute for Regenerative Medicine to year 1 pilot awardee Dr. Stanley Nelson to study a potential treatment for Duchene’s muscular dystrophy.

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

Rapid Response Team software, which was developed in year 1, was piloted on 10 multidisciplinary grant applications, of which eight are pending and one was funded. The successful proposal was led by Dr. David Reuben, who received $3.2 million from the Centers for Medicare and Medicaid Services for a project on comprehensive, coordinated, patient-centered care of Alzheimer’s disease patients.

Goal 3: Attract and enable the next generation of faculty to establish careers in team-based clinical-translational research.

As noted above, we are in the process of evaluating 24 applications for the third year of the CTSI Scholar seed grant program, which is co-funded by the DGSOM Clinical and Translational Seed Grant Initiative. We expect to award a minimum of eight seed grants of up to $50,000 under the program. In the second year, we funded 12 of these awards.

Goal 4: Recruit at least 30 new CTSI translational research faculty over the next five years.

We successfully recruited five new CTSI translational research faculty since our last progress report. Dr. Deborah Krakow was recruited to the Department of Orthopedic Surgery, Dr. Kirk Lohmueller to Evolutionary and Ecological Biology, Dr. Bogdan Pasaniuc to Pathology, Dr. Chia Soo to Surgery and Dr. Yi Xing to Microbiology, Immunology and Molecular Genetics (MIMG). Additionally, we currently have an additional 5 new CTSI recruitments pending for the Departments of Medicine (2 recruits), Pediatrics (2 recruits) and MIMG.

e. CTSA Consortium, Activities and Contributions

We are pleased to report on four accomplishments for this section over the past year: (1) We continued our funding of mental health fellowships with the University of Southern California (USC) and the Los Angeles County Department of Mental Health; (2) CTSI hosted the University of California Diversity Conference; and (3) the UCLA and University of Minnesota CTSIs joint RFA for Community Pilots was established. Up to three awards of $50,000 or more will be made Dec. 20, 2012 (see Community Engagement in Research Program for details).

f. Plans for Coming Year

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

We are in advanced discussions with the Department of Health Services in Los Angeles County (DHSCLA) to jointly fund a pilot award focused on health system improvement and efficiencies in health care delivery (see Community Engagement in Research Program). We are in the process of standardizing our reporting systems to track the ROI for pilot awards and to provide support for awardees to ensure their success.

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

The CTSI and the Business of Science Center are co-funding an Advancing Bioengineering Innovation Fellowship for graduate students, professional students and postdocs, which began in fall 2012 and will continue through spring 2013. Fellows enter the UCLA Hospital System to observe and define “unmet needs” that could be solved by a new medical device system. Guided by mentors, fellows evaluate the potential solution for prototype and business case development. The program’s strong hands-on component is expected to lead to UCLA patents and potential startup companies and translated technologies.

Goal 3: Attract and enable the next generation of faculty to establish careers in team-based clinical-translational research though the Society of the CTSI.

We expect to award a minimum of eight CTSI Scholar seed grants in 2013, and have funded 12 CTSI Scholar seed grants in 2012 as noted above.

Goal 4: Recruit at least 30 new CTSI translational research faculty over the next five years.

The recruitment committee is meeting in February, June and October to identify department and translational science needs and high-impact candidates.
UCLA CTSI
Translational Technologies and Resources Program: The Center for Translational Technologies (CTT)
Annual Progress Report (Year 2)

a. Leadership
Leader: Christopher Denny, MD
Co-leaders: Jerome Rotter, MD; Scott Filler, MD
Key personnel: Christopher Evans, PhD; Jay Vadgama, PhD; Noah Craft, MD; Clive Svendsen, PhD; Michael Teitell, MD

b. Strategic Goals of the Program
Goal 1: Implement a system for providing centralized access to and 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
Process
This program’s primary focus is to facilitate and enhance connections between translational researchers and core services across the four campuses of the UCLA CTSI partner institutions. This program has taken a federated approach that mixes a centralized structure while maintaining a certain amount of independence of the participating campuses. Dr. Denny dedicated 25% effort and Drs. Rotter and Filler dedicated 5% effort.

Progress
Significant progress has been made in creating a process for implementing a core voucher program that extends across all four campuses. Application and review forms have now been standardized. The online application and review program has been further refined and successfully used by all UCLA CTSI participants.

More than 385 applications have been received and vetted through this online process. 112 CTSI investigators have been awarded nearly $1,053,500 to utilize the 75+ CTSI technology cores. Our vouchers have led to notable contributions to clinical and translational science. For example, a year 1, $10,000 voucher to David Underhill, PhD supported research published in Science, “Interactions between commensal fungi and the C-type lectin receptor Dectin-1 influence colitis” (PMID: 22674328), and helped him obtain a four-year, $2.5-million award from NIDDK to study host immunity to commensal gut fungi. (R01DK093426). Dr. Underhill’s Science publication received a UCLA CTSI Publication Award, which recognizes our highest-impact scientific advances.

Opportunities in implementing relevant program activities
Several workshops in translational technologies were conducted in partnership with the next-generation sequencing cores. Through the “GenoSeq Core and Illumina MiSeq Application” workshop, the Fluidigm and Roche presentations on sequencing systems, the "Partek Software: Start-to-Finish Analysis Solution for NGS and Microarray Data" demonstration, and the Center for Translational Technologies Workshop, we reached more than 200 investigators from our four partner institutions, many of them from outside the David Geffen School of Medicine (DGSOM). The result was an increase in successful voucher applications from investigators outside UCLA DGSOM clinical departments to 56% (round 2) from 16% (round 1). See Figure 1 on the following page. Furthermore, by increasing awareness of available CTSI technologies, these workshops facilitated increased inter-campus utilization of core services by investigators.

Challenges in implementing relevant program activities
There have been no significant challenges other than those previously anticipated. As with all efforts that require melding of separate campuses and cultures, harmony is rarely achieved overnight. Nevertheless, as itemized below, significant progress has been made over the past year.
d. Modifications Made to Original Plan, Activities or Focus with Rationale

There have been no significant modifications to the original plan. Over the past year, the majority of effort has been directed towards Goal 1, in optimizing the utilization of core services that are already well established.

e. Major Accomplishments by Goal

Goal 1: Implement a system for providing centralized access to and ongoing performance monitoring of Translational Technology Resources (TTRs).

Over this past year, we have standardized the application and review process for the CTT core voucher system across all four campuses. Forms that meet the needs of all CTSI campuses have been developed. The online program that supports both investigator application submission as well as peer review has been further enhanced to include a discussion phase. After applications are submitted and initial reviews are completed, specific applications can be flagged for further discussion. Reviewers involved with these selected applications can now see the scores and comments of the other reviewers. With this information, they can then add comments to a discussion board for each application, and modify their scores if need be. This new feature was tested in fall 2012 Westwood/CDU voucher RFA with great success. It will be particularly useful when we implement the first cross-campus CTT voucher RFA that is scheduled for the beginning of year 3.

As of the end of this funding period, five core voucher RFAs will have been successfully conducted: Cedars-1, LA Biomed-2, Westwood/CDU-2. A total of 384 applications were processed and 112 (29%) CTSI investigators were awarded vouchers in amounts ranging from $2,000 to $10,000. Young investigators had a more favorable success rate with 41% of all young investigators being awarded and 22% of all not-so-young investigators being awarded. Significantly, there was no more than a 20% decrease in applications between the first and subsequent voucher RFAs, indicating a continued high demand.

Nearly a third of all voucher requests were for next-generation sequencing services offered by the genomics cores. Labs providing high-throughput molecular screening, proteomic services, and advanced imaging services were also highly requested. Approximately 16% of the funded requests were for inter-institutional services (see Figure 2, next page, for breakdown of core use).

Goal 2: Create an efficient mechanism for developing promising new technologies into functional TTRs.

The CTT continued to work with the UCLA Shared Resource Initiative, a program run from the office of the Vice Chancellor for Research. This program is complimentary to the CTSI’s voucher program in that it directly evaluates new and pre-existing cores and grants awards based on merit. Rather than duplicate these efforts, the CTSI has supported the Shared Resource Initiative in their mission.

Additionally in year 2, Rapid Response Team (RRT) received a Novel Translational Technologies and Methodologies (NTTM) Award of $200,000 to further develop its grant-preparation software and infrastructure. For the first 10 months of 2012, RRT’s novel software tool supported nine extramural applications; eight are pending and one received $3.2 million from the Centers for Medicare and Medicaid Services (D. Reuben, PI). CTT identified RRT as a promising new technology in year 1 (see Pilot Program report for additional detail).
Goal 3: Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs.

Over the past year, requests for high-throughput sequencing (HTS) remained one of the highest sought core services. However, the difficulty had been that there were several different cores offering HTS services using a variety of technologies. We worked with the cores to clarify and coordinate their HTS services and followed this up with an open house/lecture to educate translational investigators on the available resources.

The great popularity of HTS and genomic cores reinforced the need for biostatistical support. Though many translational investigators recognized the potential of these technologies, as a group, they were ill-prepared to effectively analyze the resulting data. On the recommendation of our External Advisory Board, we have forged closer links with the CTSI Biostatistics Program. All awarded vouchers that utilize HTS or genomic cores will automatically be eligible for support through the Biostatistics and Computational Biology (BCB) Program. In year 3, we will issue vouchers for other BCB program services.

f. CTSA Consortium Activities and Contributions

Dr. Denny participated in the Translational KFC.

g. Plans for Coming Year

Goal 1: Implement a system for providing centralized access to and ongoing performance monitoring of Translational Technology Resources (TTRs).

The first CTSI-wide voucher RFA is scheduled for the start of year 3. All the tools to carry this out are in place and have been tested at all the campuses individually. We are currently in the process of identifying reviewers; this process will be completed before the RFA.

Goal 2: Create an efficient mechanism for developing promising new technologies into functional TTRs.

We will continue to work with the UCLA Shared Resource Initiative to aid in fostering growth of new cores and recommend emerging core technologies for NTTM awards, as appropriate.

Goal 3: Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs.

The open house held for investigators interested in translational research was a clear success. Judging by the overall quality improvement in voucher applications comparing our first and second RFAs, our message was clearly heard. We plan to repeat this process prior to the opening of our campus-wide voucher RFA in early 2013. Impelling our investigators to push the limits of innovation will be our highest priority.
a. Leadership

Leader: Douglas Bell, MD, PhD

Co-leaders: Paul Fu, Jr., MD, PhD; Omolola Ogunyemi, PhD; Kent Taylor, PhD; Darren Dworkin

Key personnel: Arash Naeim, MD, PhD; Paul Silka, MD; Alex Bui, PhD; Denise Aberle, MD; Robert Dennis, MD; Virginia McFerran, MD

b. Strategic Goals of the Program

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

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. Arthur Toga resigned as BIP Director, effective May 2012, and Dr. Douglas Bell (52% effort) took on leadership of the Program. Dr. Bell is assisted by the informatics co-leaders at each partner site, Drs. Fu (Harbor-UCLA/ LA Biomed, 10% effort), Ogunyemi (Charles Drew University of Medicine and Science, 15% effort), Taylor (Cedars-Sinai Medical Center, 7.5% effort), and Dworkin (Cedars-Sinai Medical Center, 2.5% effort). A major focus for the Program has been responding to recommendations from the EAB to prioritize the RDR efforts and to de-emphasize researcher networking and other projects that could distract from success of the RDR.

For the Virtual Home (Goal 1), support for system hosting was shifted to the Computing Technologies Research Lab (CTRL) at UCLA. Support for hosting the RDR (Goal 2) was shifted to UCLA’s Medical Information Technology Services (MITS) and the UCLA Academic Technology Service (ATS). For Goal 3, Drs. William Hsu and Alex Bui joined the team to develop the informatics curriculum described in section e. of this progress report. Also, Moodle support was migrated to UCLA’s Office of Information Technology (OIT), which maintains Moodle for the entire campus.

c.2. Progress

For the CTMS, the selection process continues. We have compared open-source partial solutions from other CTSA’s, such as SPARC and Harvard Catalyst Scheduler and Protocol Systems, as well as commercial systems, including OnCore (Forte Research Systems), Velos eResearch (Velos), and Click Commerce (Huron Consulting Group). Please refer also to section e. of this report for progress to date on each of the strategic goals.

c.3. Opportunities in Implementing Relevant Program Activities

UCLA is participating in the University of California Research eXchange (UC-ReX), a project of the UC Biomedical Research Acceleration, Integration, and Development (UC BRAID), which is the coalition of the five University of California (UC) medical campuses with CTSA’s. UC-ReX is developing a secure online system that enables clinical investigators to identify potential research study cohorts across the five UC medical centers. UCLA’s participation in UC-ReX has provided an opportunity to accelerate our achievement of Goal 2, leveraging the extensive RDR experience of the other UC CTSA’s.

c.4. Challenges in Implementing Program Activities

With respect to the RDR, the availability of clinical data from UCLA Health Sciences was delayed due to IT staff being diverted to Epic EHR implementation. However, with assistance from the CTSA, UCLA launched its “xDR” Enterprise Data Warehouse project, with its initial top priority being the provision of de-identified clinical
data for the UC-Research eXchange (UC-ReX) project, described below. Initial population of data into the xDR and into UC-ReX is now nearly complete, as described in section e., below.

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

The UC-ReX project will meet the CTSA’s RDR goals of supporting research hypothesis generation, grant preparation, and patient recruitment, but because it will not link patient identities across institutions, it will not effectively support epidemiologic or comparative effectiveness research. Thus, we have launched a new project, the Los Angeles Data Repository (LADR), which will create a pooled repository of linked clinical data, initially from the CTSI partners and eventually from all institutions in the Los Angeles region, for conducting region-wide comparative effectiveness research with outcomes gathered from the multiple institutions that patients visit. The project’s ultimate goal is to improve the health of the Los Angeles region, which is also the overarching goal of the CTSI.

e. Major Accomplishments by Goal

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

The Virtual Home (VH) is a central website for information and services provided by the CTSI. We re-implemented all VH content from the site maintained by Dr. Toga’s group to a new content management system that enables delegation of page management to appropriate program personnel. We re-implemented single sign-on using UCLA’s campus-wide Shibboleth authentication system. Replacing last year’s effort, VITAE, we adopted an existing faculty database to create UCLA Profiles. We also interfaced the UCLA Profiles system with the national DIRECT2Experts system. The VH also handles applications for CTSI support opportunities such as the pilot funding programs and vouchers for use of core resources.

From 6/25/12-11/9/12, the VH has had 14,893 hits made by 6,310 unique visitors. Annualized, this would be a rate of 39,390 visits per year, a 55% increase from the usage reported last year. Sixty percent of hits are return visits, and the site has had 86,328 page views.

Finally, we created and launched the Team Science Workflow System (TSWS), an online system that coordinates and tracks research facilitation efforts and other scientific collaborations from the earliest stages of exploration through to ultimate outcomes such as funded projects or published manuscripts. The system recently went live with four CTSI programs.

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 UC-ReX, we completed implementation of an i2b2/SHRINE query system and connected it to the other UCs. As of 11/15/2012, UCLA’s local i2b2 component has been populated with patient demographic data, encounter diagnoses and procedure data from the UCLA Health System. The system is undergoing final testing and is expected to be ready for initial use by investigators before the end of 2012.

For LADR, we have held meetings with our partner institutions to achieve buy-in at the user level and are now focusing on upper management. To date, we have recruited five pilot studies to serve as driving projects. We are in the process of negotiating a consortium agreement and user agreements with our partner institutions. We have also already begun coordinating with our partner institutions and LA County to have the County contribute to/access the repository. Last, we are currently working with our partner institutions to design a study comparing patient linkage algorithms.

UCLA’s own clinical data contributions to UC-ReX and LADR will come from the Health System’s xDR project, which is developing a central “data trust” to serve as the single best source of data for research, analytics and management of health system operations. The project involves establishing data systems, reference terminology systems, and data quality/integrity checks. It will bring together data from the CareConnect EHR system that will go live on March 1, 2013 with data from the “legacy” systems that CareConnect will replace. To date, the xDR Data Trust has been populated with seven years of encounter data from UCLA’s legacy systems in order to provide initial data for the UC-ReX project.

Goal 3: Provide training in informatics tools and methods.
Collaborating with the CTSI Research Education, Training, and Career Development Program, we have developed three three-hour informatics workshops that will be presented in spring 2013. They will be part of the Track 1 curriculum of the Training Program in Translational Science, open to all interested at any partner institution. The three workshops are (1) Introduction to Biomedical Informatics, (2) Data Standards & Terminologies, and (3) Practical Tools in Informatics. The first familiarizes participants with the basic principles of biomedical informatics with a focus on principles applicable to ongoing projects and services across the CTSI sites. The second describes the use of data standards for representation and exchange of clinical information and the increasing use of controlled vocabularies and ontologies to annotate content. The third provides hands-on experience with CTSI-specific tools and other popular applications that facilitate the management and analysis of clinical and experimental data.

f. CTSA Consortium Activities and Contributions

Dr. Bell attended the CTSA Informatics Key Function Committee Meeting in Chicago in November 2012, where he learned of the latest progress and activities of established CTSAs. He also presented a poster on the TSWS.

g. Plans for Coming Year

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

We have started planning the implementation of the Eagle-i resource discovery system in order to better connect our UCLA researchers with resources at our partner CTSIs and elsewhere. For TSWS, we will roll the system out to the remaining UCLA CTSI cores and partner sites, collecting feedback and incorporating changes along the way. We aim to make the system as user friendly as possible in order to promote adoption and streamline the research facilitation process. Our goal is to capture 100% of service requests within the system by early 2013 and to report on the system’s uptake and utility at the next IKFC meeting. For UCLA Profiles, we will link the database to portal accounts and enable researchers to edit their own profiles.

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 UC-ReX, we will add lab results and certain inpatient medications to the data available for patient cohort selection. We will pilot test the cohort discovery system with early users. Following this testing, we will make the system available to CTSI investigators for self-service queries after they complete training on the system. We will track the success of proposals that are submitted based on preliminary data from UC-ReX. We will also design and build a system for recruiting patient cohorts that are identified through UC-ReX after the investigator receives IRB approval for the proposed study.

For LADR, we will complete the technical development of the system, and we will also conduct a study comparing patient linkage algorithms, which will result in a completed manuscript by November 2013.

For CTMS, we will complete architecture design, plans for integrating with Epic, and purchasing for commercial software components. We will also implement software and train initial users.

Goal 3: Provide training in informatics tools and methods.

We will implement the Track 1 informatics seminar series described above. We will also work to create an expanded course offering for the certificate program in Clinical & Translational Research and the Track 3 Masters of Science in Clinical Research curriculum. We will also offer educational activities on the UC-ReX (SHRINE) cohort discovery tool, and we will continue to support the Moodle course management system for the Education Program.
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

Process
Dr. Mangione (20% 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 (7.5% effort), Dipple (10% effort) Edelstein (5% effort), Fine (10% effort), Sun (5% effort), Wang (8.5% 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 (5% effort) is director of the Training Program in Translational Science; Drs. Wilkerson (5% effort) 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.

Progress

Opportunities and Challenges in Implementing Relevant Program Activities

The CTSI-ED office continues to operate efficiently under direction of Drs. Mangione and Wong with administrative support from Ms. Lisa Chan and Mr. William Lee. It has been a challenge to merge the different cultures of the four CTSI partners since each institution has its own grants-management system and opportunities for educational activities. We are making significant progress to establish the cross-institutional relationships. For example, we ensure that our committees and working groups (CREST, KL2 Selection, TL1 Summer Selection, STAR Expansion, and High School Pipeline) have representation from each of the partner institutions. Decisions made by these committees and working groups require the consensus from each institution. In response to the External Advisory Board (EAB) comments, we have implemented an ongoing evaluation process and review reports to identify successful aspects of our training programs and potential gaps. Two efforts that draw on the collective experience and strengths of our institutions—the NIH-funded P30 center on minority aging, a UCLA-Charles Drew University of Medicine and Science (CDU) collaboration that has lasted more than 10 years, and our high school pipeline programs—provide CTSI a unique opportunity to recruit and train minority scholars (see below).
We have seen a very large interest from trainees in grant writing based on their challenges to obtain funding and gain scientific independence. In response, we have implemented a new K-award writing workshop that has been very popular and successful (see KL2 Program Report). Our year 2 activities are as follows:

**KL2 & TL1 Programs (Goals 1 & 2).** In Year 2, the CTSI-ED successfully selected 3 new KL2 Translational Science Scholars, 5 new TL1 Translational Science Pre-doctoral Fellows and 20 TL1 Summer Professional Students (Please see the KL2 and TL1 Program Reports elsewhere in this document for details).

**TPTS (Goal 2).** The Training Curriculum Program has been renamed to the Training Program in Translational Science (TPTS) and remains under the direction of Dr. Isidro Salusky. The TPTS continues to offer three 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 there are 100 trainees enrolled in Track 1 (with 28 applicants in 2012), 30 enrolled in Track 2 (with 12 trainees accepted in 2012), 23 enrolled in Track 3 (with 9 trainees accepted in 2012), and 58 medical students (with eight trainees accepted in 2012). The curriculum committee identified a need for seminars on comparative effectiveness research and four modules have been added to Track 1 focused on patient-centered outcomes of health care, community characteristics & GIS, implementation science, and cost-effectiveness analysis.

**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 eventually allow us to implement more courses via distance learning. In spring 2012, we pilot-tested Moodle with 2 TPTS courses (Biomath 258 & M263), and in fall 2012, we implemented Moodle for all TPTS Track 3 courses. CTSI-ED will continue to work closely with the CTSI Evaluation Program to finalize the UCLA CTSI core competencies and move forward with aligning them with the TPTS courses available on Moodle.

**STAR Expansion (Goal 2).** We identified representatives from each of the UCLA CTSI partners to participate in the Subspecialty Training and Advanced Research (STAR) Program Expansion Subcommittee to discuss mechanisms to extend the highly successful UCLA STAR Program to their institutions. The main barrier for the expansion is funding tuition costs for trainees to obtain a graduate degree from UCLA. We plan to develop and submit T32 grant applications at the partner institutions to fund training expenses for the STAR Expansion Fellows. The STAR Expansion Subcommittee members include: Drs. Carol Mangione (UCLA), Mitchell Wong (UCLA), Linda Demer (UCLA), Leon Fine (Cedars-Sinai Medical Center), Jay Vadgama (CDU), and Michael Yeaman (Los Angeles Biomedical Institute at Harbor-UCLA Medical Center; LA BioMed).

**High School Pipeline (Goal 2).** The High School Pipeline Working Group 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.

**Minority Aging Research Collaboration (Goals 1 & 2).** The CTSI collaborated with the UCLA/CDU Resource Centers for Minority Aging/Center for Health Improvement for Minority Elders (RCMAR/CHIME) to co-fund 4 pilot investigators to conduct Type 2 translational research focused on minority aging research. RCMAR/CHIME has been successfully renewed by the NIA in September 2012. The CTSI will continue to provide co-funding for 3 pilot investigators per year. RCMAR/CHIME holds tri-annual scientific retreats and offer monthly methodological seminars focused on health disparities research. Trainees may submit writing drafts (i.e. manuscripts, proposal) to be reviewed by senior faculty and discussed at the Retreat. This collaboration has been a catalyst in developing and strengthening our relationship with CDU.

**K/Career Development Award Grant Writing Workshop (Goals 1 & 2).** We developed a series of all-day K-award grant writing workshops opened to junior investigators at the UCLA CTSI partner institutions. The first workshop was held on July 26, 2012 at UCLA. We plan to offer these workshops quarterly and rotate the venue at each CTSI partner institution. (Please see the KL2 Program report elsewhere in this document for more details).
d. Modifications Made to Original Plan, Activities or Focus with Rationale
There have been no major modifications to the original plan.

e. Major Accomplishments by Goal

Goal 1: Integrate community input and involvement into research training activities.
One KL2 scholar and three TL1 pre-doctoral trainees have identified community mentors for their research projects. (Please see the KL2 and TL1 Program Reports elsewhere in this report for more details). All of our trainees participate in the CREST Committee meetings where they present their work in progress.

Goal 2: Transform translational education.
As noted above, we have selected the new cohorts of KL2 scholars, TL1 pre-doctoral and summer trainees. We have also developed Career Development Award Workshops and collaborated with RCMAR/CHIME to provide interdisciplinary venues for our trainees to meet faculty and potential community mentors. In addition, the TPTS continues to attract junior investigators from all CTSI partners.

Goal 3: Provide mechanisms to integrate patient-oriented research training through the CTSI Curriculum Tree.
As noted above, we have successfully piloted Moodle and started to align the UCLA CTSI core competencies to the TPTS courses.

f. CTSA Consortium Activities and Contributions
Drs. Mangione and Wong continue to be regular participants in the National Key Functions Committee (KFC) for the CTSA Education and Career Development program directors. Dr. Wong also attended the Education KFC Face-to-Face Meeting on Apr. 18, 2012 in Washington, DC. Drs. Mangione and Wong will continue their active participation in both the National KFC and regional consortium.

g. Plans for Coming Year

Goal 1: Continue to integrate community input and involvement into research training activities.
• Collaborate with the Community Engagement Research Program (CERP) to reach out to the community, incorporate their participation in the CTSI-ED trainees’ research, and have each trainee present at least once at a community venue. The community mentors can also collaborate on the trainees’ projects.
• Partner with CERP to identify community mentors for each TL1 dissertation committee and each KL2 project where appropriate.
• Increase number of promising junior scientists to apply for CERP community capacity-building projects.

Goal 2: Continue to transform translational education.
• Continue our KL2 and TL1 Programs (see KL2 and TL1 reports elsewhere in this document).
• Review curriculum mapping to the competencies to expand the TPTS to address other research topics, which include biomedical informatics.
• Work with the STAR Program Expansion Subcommittee to help the UCLA CTSI partner institutions develop and submit T32 grant applications to cover for training expenses at their sites.
• Convene High School Pipeline Writing Group to develop a report on best practices and long-term outcomes across the existing pipeline programs in year 3 and for dissemination by the end of year 4.
• Partner with CERP/HSR to develop the seminar series in translational research methods to include topics on implementation science, advance statistics, and community-based participatory research.
• Assess the need for a formal mentors training program in partnership with the UCLA DGSOM Dean’s Office to train a council of advisors on mentoring and career guidance.
• Increase integration of training programs to promote multi-level and daisy chain mentoring for the trainees at different career points.

Goal 3: Continue to provide mechanisms to integrate patient-oriented research training through the CTSI Curriculum Tree.
• Complete the implementation of Moodle for all TPTS courses to include Tracks 1 & 2 by the end of year 3.
• Increase the number of trainees at the partner institutions by 10% to complete the TPTS curriculum using distant learning options.
• Develop a system to monitor evaluate the processes and outcomes of the distance learning technologies.
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

Process
Dr. 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. Mangione (20% effort). Ms. Lisa Chan (100% effort) is the program administrator and Mr. William Lee (25% effort) provides administrative support.

Progress

Opportunities and Challenges in Implementing Relevant Program Activities
We have awarded our second cohort of three KL2 Scholars from an outstanding pool of 28 applicants: 15 from basic science, 18 from clinical research and five from health services research. They have strongly committed mentors who are receptive to adding CTSI mentors to each scholar’s multidisciplinary mentorship team as needed to strengthen the science. (Please see the Trainee Progress Reports elsewhere in this document for more detail). 64% of the applicants were male, 36% were female and 11% were minority. We continued to use an online submission process and convened a Selection Committee. We are collaborating with the CTSI Community Engagement Research Program (CERP) to identify the best community mentors for our KL2 Scholars.

Our 2012 KL2 Scholars (started on July 1, 2012) are:

- **James A. McKinnell, MD** is an Assistant Professor of Medicine at LA BioMed Harbor-UCLA in the Division of Infectious Diseases. The title of his project is “Using Research in Vancomycin-Resistant Enterococcus to Validate an Efficient System of Quantifying Antibiotic Utilization.” His mentors include Drs. Loren G. Miller (LA BioMed), Susan S. Huang (UC Irvine) and Martin F. Shapiro (UCLA).

- **Mary E. Sehl, MD, PhD** is an Assistant Clinical Professor of Medicine at UCLA in the Division of Hematology-Oncology. The title of her project is “Modeling of EMT/MET transitions in breast cancer stem cells.” Her mentors include Drs. Kenneth Lange (UCLA), Gay Crooks (UCLA) and Max Wicha (University of Michigan).

- **David B. Shackelford, PhD** is an Assistant Professor Medicine at UCLA in the Division of Pulmonary and Critical Care Medicine. The title of his project is “Development of novel therapeutic strategies to target LKB1/STK11 deficient non-small cell lung cancer.” His mentors include Drs. Steven M. Dubinett (UCLA, Director of CTSI) and Hong Wu (UCLA).

One of the KL2 applicants from this cycle was awarded a K23 from the NIH National Institute on Aging, Paul B. Beeson Career Development Award. He will be included in all CTSI Education events.

- **Gerardo Moreno, MD, MSHS** is an Assistant Clinical Professor at UCLA in the Department of Family Medicine. His K23 project title is “Health IT decision support to improve medication management safety and quality.” His mentor is Dr. Mangione (UCLA, Director of CTSI Education Program).

Our 2011 KL2 Scholars (started on January 1, 2012) are:

- [List of names and projects], which includes [detailed information about each scholar].
Amira K. Brown, PhD, MD is an Assistant Professor of Medicine at CDU in the Department of Internal Medicine. The title of her project is the “Effects of Varenicline on Alcohol and Nicotine Consumption and changes in Dopamine D2-like Receptor Availability in High-Alcohol Preferring Mice.” Her mentors include Drs. Theodore Friedman (CDU) and Mark Mandelkern (VA). Dr. Brown has published two peer-reviewed manuscripts since she started her training.

Gelareh Z. Gabayan, MD, MSPH is an Assistant Professor of Medicine/Emergency Medicine at UCLA and West Los Angeles Veteran’s Administration, and Director of Quality Assurance for the West LA Emergency Department. The title of her project is “Patterns and Predictors of Poor Outcomes Following Emergency Department Discharge in Older Adults.” Her mentors include Dr. Catherine A. Sarkisian (UCLA), Arthur Kellerman (RAND) and Jerome R. Hoffman (USC). She also been working with her community mentors from Kaiser Permanente: Drs. Stephen Derose (up until June 2012) and Michael Gould (June 2012 to present). Dr. Gabayan has published one peer-reviewed manuscript since she started her training.

Joshua J. Zaritsky, MD, PhD is an Assistant Professor in Pediatric Nephrology at UCLA. The title of his project is “Hepcidin and the Anemia of Chronic Kidney Disease,” mentored by Drs. Isidro Salusky (UCLA), Tomas Ganz (UCLA) and Kamyar Kalantar-Zadeh (LA BioMed). Dr. Zaritsky has published seven peer-reviewed manuscripts since he started his training.

We launched the first NIH K/Career Development Award Workshop on July 26, 2012 at UCLA. 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: Drs. Dubinett, Mangione, Salusky, Keith Norris, and Wong. A panel discussion was also held during the lunch hour with recent K awardees describing their personal experiences and providing useful tips on developing a successful K award application. The panelists included: Drs. Kenrik Duru, Edward Garon, Brigitte Gomperts, and Jonathan Wanagat. 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 award applications. The workshop was attended by 58 junior investigators and 14 of them submitted draft K award applications for review. We conducted pre- and post-workshop surveys and the event was extremely well received (see diagram below). The junior investigators who participated in the review/discussion session of draft applicants found it very beneficial to meet with their reviewers and get in-person feedback.

A challenge of the KL2 Program has been recruiting more applicants from outside UCLA-Westwood. In the last application period, we received five from Cedars-Sinai, one from CDU, three from LA BioMed, and 19 from UCLA. We plan to work closely with the education leaders at the partner institutions to develop a better plan for advertisement and recruitment of junior investigators to apply for the KL2 Program.
d. Modifications Made to Original Plan, Activities or Focus with Rationale
There have been no major modifications to the original plan.

e. Major Accomplishments by Goal

Goal 1: Recruit outstanding scholars with the potential to become leaders in translational science.
As noted above, we have selected three new KL2 Scholars (McKinnell, Sehl, Shackelford) and one KL2 applicant (Moreno) received an NIH/NIA-funded K23 award.

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 would expand their knowledge and expertise. For example, Dr. Gabayan is enrolled in the CTSI Training Program in Translational Science (TPTS) Certificate Program; Dr. Zaritsky is pursuing a Masters of Science in Clinical Research (MSCR) through the TPTS; and Dr. James McKinnell is enrolled in the Masters of Science in Health Policy and Management (MSHPM) through the UCLA School of Public Health. Drs. Brown, Sehl and Shackelford have plans to take individual courses at UCLA as well as workshops/seminars available through their department or annual professional conferences.

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 other agencies.
As noted above, we held a NIH K/Career Development Award Workshop to help junior investigators understand the development and submission of career development awards. The goal is to offer these workshops quarterly on a rotating basis at all partner institutions. The next workshop is scheduled for Jan. 10, 2013 at LA BioMed at Harbor-UCLA. As noted in the CTSI-ED Report, UCLA/CDU RCMAR/CHIME holds tri-annual Scientific Retreats, which include review/discussion sessions of draft proposals. The last Scientific Retreat was held on Oct. 29, 2012 and Dr. David Shackelford submitted his draft proposal to the Addario Lung Cancer Foundation which was reviewed by Drs. Thomas Graeber and Sherven Sharma from UCLA’s Jonsson Comprehensive Cancer Center.

f. CTSA Consortium Activities and Contributions
Dr. Wong participates on the monthly Mentored Independent Scholar Meeting- K to R Work Group webinars.

g. Plans for Coming Year

Goal 1: Recruit outstanding scholars with the potential to become leaders in translational science
• Continue the KL2 program and collaborate with the UCLA Broad Center Stem Cell Center to fund additional training slots for junior investigators to conduct translational science.
• Increase communication with the education leaders at Cedars, CDU and LA BioMed to better market the KL2 program and include in-person visits to the different CTSI institutions to recruit and encourage young 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.

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 MSCR and MSHPM.
• Increase formal career mentoring for KL2 scholars to help with their transition to becoming independent scientists.

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 other agencies.
• Offer the NIH K/CDA Workshops quarterly to provide mock study sections and early grant reviews from senior faculty.
• Increase the number of KL2 Scholars to attend the UCLA/CDU RCMAR/CHIME and CDU/UCLA Project EXPORT Scientific Retreats and monthly Methodological Seminar Series.
• Develop seminars and workshops focused on the NIH K to R award transition.
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; and 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
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 Professional Students. Both fellowships fall under the Research Education, Training, and Career Development Program, which is directed by Drs. Carol Mangione (20% 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.

Progress
Opportunities and Challenges in Implementing Relevant Program Activities
We have identified and awarded five new TL1 pre-doctoral fellows from an outstanding pool of 40 PhD applicants in the Department of Health Policy and Management (HPM) at the UCLA School of Public Health. 15% of the applicants were from minority populations, 33% were male and 67% 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 document for more detail).

Our 2012 TL1 Pre-doctoral Fellows are:
• Anna Davis, MPH was admitted to the doctoral program in fall 2012.
• Sarah Friedman, MSHS was admitted to the doctoral program in fall 2012.
• Lauren Gase, MPH was admitted to the doctoral program in fall 2012. She is currently working with the Los Angeles County Department of Public Health (Division of Chronic Disease and Injury Prevention). Her community mentor is Dr. Tony Kuo, who is deputy director of the division.
• Charleen Hsuan, JD was admitted to the doctoral program in fall 2010. Her project title is “Organizational Determinants of Noncompliance with Two Federal Health Care Laws” under the mentorship of Dr. Hector Rodriguez (UCLA).
• Diane Tan, MSHS was admitted to the doctoral program in fall 2012.

Our 2011 TL1 Pre-doctoral Fellows are:
• Erin Hahn, MPH is currently working on her project, “Cancer Survivors and Survivorship Care” and her mentor is Dr. Patricia Ganz (UCLA). Her community mentors are Miriam Sleven and Char Cottrell at Torrance Memorial Hospital, and Marian Hemmelgarn and Dr. Melinda Maggard-Gibbons at Olive View-UCLA Medical Center. Erin has published one peer-reviewed manuscript since she started her training.
• Audrey Jones worked on her project, “Reducing the Burden of Chronic Depression among Racial/Ethnic Minority Populations,” with her mentor Dr. Vickie Mays (UCLA). Ms. Jones completed her TL1 training on 8/31/12 to accept an R36 AHRQ dissertation award that began on 9/1/12.
Jenna Jones, MPH continues to work on her project, “Hospitalization patterns and emergency department use during transition period: analysis of experience for those with chronic illnesses,” with her mentor, Dr. Nadereh Pourat (UCLA). Jenna has published one peer-reviewed manuscript since she started her training.

Alice Villatoro is working on her project “Mental Illness Careers of Racial-Ethnic Minorities in the United States: The Case of Perceived Need for Mental Health Care” with her mentor, Dr. Ninez Ponce (UCLA). Her community mentor is Dr. Herb Hatanaka, executive director of Special Services for Groups (SSG) and adjunct professor at USC’s School of Social Work.

We have also selected 20 health professional students (medical, dental, nursing) for the TL1 Summer Fellowship from a pool of 27 applicants. 37% of the applicants were from minority populations, 37% were male and 63% were female. The summer students are either funded through the CTSI TL1 grant or institutional funding from UCLA. The 20 students were paired with senior research mentors, participated in an eight-week summer didactic program in interdisciplinary and health disparities research, and presented their findings at the Josiah Brown Poster Fair or Dental Students Poster Session. (Please see the Trainee Progress Reports elsewhere in this document for more detail).

Our 2012 TL1 Summer Fellows are:

- Jane Agu (CDU MSN), Mentor: Dr. Martin Shapiro (UCLA).
- Alejandra Bautista (CDU/UCLA MD), Mentor: Dr. Jeanne Miranda (UCLA)
- Lubabah Ben-Ghaly (UCLA MD), Mentor: Dr. William Cunningham (UCLA)
- Michael Hoang, David Lee & Laura Van (UCLA DDS), Mentors: Drs. Carl Maida & Marvin Marcus (UCLA)
- Christine Kho (UCLA MD), Mentor: Dr. Mitchell Wong (UCLA)
- Catherine Kim & John Brandon Pierce (UCLA DDS), Mentor: Dr. Nadereh Pourat
- Michael Mangubat (CDU MD), Mentor: Dr. Theodore Friedman (CDU)
- Adrienne Martinez-Hollingsworth (CDU MSN), Mentor: Dr. Patricia Humbles (CDU)
- Ozioma Nwosu (CDU MSN), Mentor: Dr. David Martins (CDU)
- Amarachi Okoro (UCLA MD), Mentor: Dr. Michael Rodriguez (UCLA)
- Mark Ortega & Rebecca Paddack (UCLA DDS), Mentors: Drs. Carl Maida & Marvin Marcus
- Walter Perez (CDU MSN), Mentor: Dr. Theodore Friedman (CDU)
- Amy Tam & Olivia Yue (UCLA DDS), Mentor: Dr. Jennifer Holtzman (UCLA)
- John Thanasukarn (CDU/UCLA MD), Mentor: Dr. Ashaunta Tumblin (UCLA)
- Khoa Tran (UCLA DDS), Mentor: Dr. James Crall (UCLA)

It was challenging to coordinate and schedule an eight-week course in health disparities research since the UCLA School of Medicine is on a semester system and the School of Dentistry (SOD) is on a quarter system. The medical students’ summer calendar runs from early June to late July. The dental students’ summer calendar runs from early July to the late August and they have also mandatory summer courses for their professional program. We worked with Drs. Carl Maida and Marvin Marcus from the SOD to develop a parallel program for the dental students to participate in during their summer quarter. We were able to negotiate institutional co-funding from the UCLA CTSI and SOD to fund seven additional dental students for the summer program.

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

As noted above, we developed a parallel TL1 summer program for the UCLA dental students.

**e. 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 recruited pre-doctoral candidates at the 6/10-6/13/12 American Society of Health Economist Conference in Minneapolis. We also invited current TL1 Pre-doctoral Fellow, Lauren Gase, to visit UCLA in
March 2012 when she was able to meet with the Department of Health Policy & Management faculty and CTSI CREST Committee members. Dr. Cunningham recruited medical students at the David Geffen School of Medicine’s Summer Research Opportunities Fair in January 2012 and strongly encouraged minority students from the CDU/UCLA medical and PRIME programs to apply.

**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 Health Policy and Management, the program offers didactic coursework in research methodology, outcomes research, health policy, and community-partnered research. For the Summer Fellows, Drs. Cunningham and Michael Rodriguez (co-teacher from Project EXPORT) developed an eight-week seminar series focused on health disparities research. Drs. Carl Maida and Marvin Marcus used a similar curriculum for the dental students. The trainees completed an evaluation at the end of the program and the curriculum was very well-received.

**Goal 3: Recruit the most qualified faculty as mentors for trainees and fostering interactions between fellows and faculty.** We have identified a list 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 24 faculty members from different departments who were willing to mentor TL1 summer fellows. Drs. Maida and Marcus also convened a group of five SOD faculty to mentor the dental summer students’ research teams. All the 2011 TL1 pre-doctoral fellows presented their research at CTSI CREST Committee Meetings where they were able to get feedback from faculty. As noted in the CTSI-ED Report, all CTSI trainees were invited to attend and participate in the Scientific Retreats, which were held on 4/16/12 and 10/29/12. For the 10/29/12 Retreat, Alice Villatoro (PhD student), submitted her dissertation prospectus to be reviewed by faculty. Medical students, Lubabah Ben-Ghaly and Amarachi Okoro, also participated in a poster session at the Retreat.

**f. CTSA Consortium Activities and Contributions**

Drs. Mangione and Wong continue to be regular participants in the National Key Functions Committee (KFC) for the CTSA Education and Career Development program directors. They attend all regular monthly KFC webinars and brief Drs. Ettner and Cunningham for any issues that come up regarding the TL1 programs.

**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.**

- Improve communication with the education leaders at CDU and UCLA to better advertise and increase the number of applications from health profession students for the TL1 Summer Program.
- Instead of running a separate track for the dental students, develop a single health disparities course to include all medical, dental and nursing TL1 summer fellows to foster multi-disciplinary interactions for the TL1 Summer Program.
- 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, such as the K/Career Development Award Workshops, RCMAR CHIME/Project EXPORT/CTSI 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.
- Continue to invite CTSI TL1 trainees to attend CREST Committee Meetings or other events so they have the opportunities to interact and network with other CTSI trainees (i.e., KL2 & CHIME Scholars) and faculty.
a. Personnel

Leaders: Pamela Davidson, PhD

Co-Leaders: Mohsen Bazargan, PhD; Lourdes Guererro, EdD; Moira Inkelas, PhD, MPH; Gerald Kominski, PhD; Deborah Konik-G-Giffin, 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 an Improvement Sciences Program with the intent of increasing efficiency, stimulating innovation and improving operational effectiveness in the CTSI and its community research centers.

Goal 3: Create the UCLA CTSI Center for Evaluation and Health Services 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

Process

The Evaluation Program is led by Dr. Davidson (45% effort), who is responsible for oversight of all Evaluation aims, serves on the CTSA Evaluation KFC and CTSI Operations Committee. Four faculty serve as Evaluation co-leaders from the partner institutions: Drs. Mohsen Bazargan (5% effort) from Charles Drew University, Loren Miller (10% effort) from Harbor-LA Biomed, Michael Weismann (7.5% effort) and Alisa Wilson (10%) from Cedars Sinai Health System. The Evaluation co-leaders at UCLA are Drs. Moira Inkelas (10% effort), Jack Needleman (5% effort), Deborah Konik-G-Giffin (20% effort), Gerald Kominski (2.5% effort) and Lourdes Guererro (100% effort). Our faculty leaders from the four partner institutions form a Faculty Advisory Board.

Our major evaluation activities continue to be: (1) document the transformation, (2) monitor progress against plan, and (3) longitudinally track performance and outcomes. We provide data analysis to inform leaders about emerging opportunities and challenges. Additionally, we provide systematic information to create data-driven strategies and solutions to advance the research enterprise. We have designated team members who are responsible for collecting qualitative and quantitative data to evaluate the extent of goal achievement for each of the five CTSI institute goals. Besides our faculty, our team in includes research staff: Nicole Makowka, Jim Morrison, Terry Nakazono, and Jordan McCrary. Table 1 (next page) summarizes the CTSI goals, evaluation data sources, sample metrics, and faculty/staff responsibilities for managing data collection and reporting progress.

Progress: Opportunities and challenges in implementing relevant program activities

In May 2012, our CTSI External Advisory Board (EAB) commented on the strengths and assets of the Evaluation Program, as follows: (1) the organizational change framework that is the underpinning for the Evaluation Plan is most appropriate given the complex, adaptive nature of CTSA infrastructure development; (2) the organizational behavior and organizational development expertise of the Evaluation director to lead this effort coupled with Health Services Research expertise distributed across other components; and (3) metrics linked to each goal include a mix of outputs, outcomes, and process measures using mixed-method evaluation that is well planned.

Our response to the major weaknesses and challenges identified by the EAB are summarized, as follows:

(1) “To deal with the complex, adaptive nature of the CTSA as a large-scale research enterprise, it may be beneficial to consider weaving evaluation efforts with its ongoing development...” In 2012 the Evaluation Program leadership participated in weekly meetings with the CTSI Operations Committee; attended by the PI and other leadership, these meetings are the primary forum for sharing evaluation results and responding to data collection and analysis requests to inform leadership decision-making; (2) EAB stated “this utilization-focus also implies that evaluation should directly feed into governance and high-level decision-making to
accommodate fluid and frequent changes in course...” Our Evaluation Program is embedded in the Executive Oversight Committee (EOC) and Operations Committee; these have been the most effective structures to ensure utilization-focused evaluation in year 2. (3) “Given the enormous amount of data to be collected, it may be advantageous to consider leveraging the use of Business Intelligence (BI) tools...and integrate complex data often buried deep within institutions and their affiliates...” In 2012, we explored BI tools, such as Elsevier Sci-Val Suite; we are considering the viability of purchasing the software through the University of California Office of the President. Additionally, we identified existing data sources useful for evaluation, e.g., Technology Transfer and Office of Research Administration. (4) The Evaluation Plan might benefit from the inclusion of “emerging opportunities and unanticipated outcomes...” We are creating evaluation plans in response to emerging leadership strategy regarding organizational restructuring, entrepreneurial opportunities, and ensuring integration of all partners.

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

In year 2, we disaggregated the personnel and budget for the evaluation and health services research (HSR) functional areas. We realized HSR and Evaluation research priorities were too different to form a coherent research unit. HSR priorities were found to align with the Community Engagement in Research Program, (CERP), so HSR faculty and personnel were consolidated in CERP. Consequently, the Evaluation Program has refined Goal 3, which provides the scientific foundation of the program and represents our sustainable business model. Two-thirds of Goal 3 milestones have been met: (1) center is functional and (2) participate in at least 1 proposal/year. In year 3, we will conduct an e-survey to document need for evaluation services and expertise.

e. Major Accomplishments by Program Goal

In year 2, we collaborated with all CTSI leaders to identify priorities and a set of metrics to monitor progress toward goal achievement. The year 2 findings from this analysis are reported in section a of the CTSI Self-Evaluation.

Goal 1: Longitudinally track and evaluate initiative and program outcomes. Our approach is summarized in Table 1 below (* denotes proposed year 3 evaluation data sources).

<table>
<thead>
<tr>
<th>CTSI Goals and Evaluation Questions</th>
<th>Sample Evaluation Data Sources</th>
<th>Sample Metrics</th>
<th>Point Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 1. Create an academic home for clinical and translational science</td>
<td>Org Effectiveness/Investigators Needs Assessment</td>
<td>Utilization, Satisfaction</td>
<td>Morrison</td>
</tr>
<tr>
<td>How did we create and sustain an academic home?</td>
<td>Team Science Workflow System (TSWS)*</td>
<td>Organizational Efficiency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Webcamp, OnCore Clinical Trial Management System (CTMS)<em>, REDCap</em></td>
<td>Effectiveness</td>
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<td></td>
<td>WebIRB, Office of Research Administration (ORA)<em>, and Campus Data Warehouse/Query Database</em></td>
<td>Integration, Cost, Reimbursement</td>
<td></td>
</tr>
<tr>
<td>Goal 2. Transdisciplinary research teams to accelerate and translate discovery to improve health</td>
<td>Scientific Productivity survey*</td>
<td>Institutional Support</td>
<td></td>
</tr>
</tbody>
</table>
## CTSI Goals and Evaluation Questions

<table>
<thead>
<tr>
<th>Goal 4. Bi-directional communication with Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>To what extent did we create a sustainable infrastructure for conducting community-partnered research?</td>
</tr>
<tr>
<td>- CTSI Community Partner Survey</td>
</tr>
<tr>
<td>- Infrastructure evaluation and process/pathway mechanisms for effective academic/community interface*</td>
</tr>
<tr>
<td><strong>Sample Evaluation Data Sources</strong></td>
</tr>
<tr>
<td>CTSI Community Partner Survey</td>
</tr>
</tbody>
</table>
- # and type of community research partners | Inkelas |
- # of community trials | Guerrero |
- # projects | McCrory |
- # participants recruited | |

## Goal 5. Create the Regional Laboratory for conducting translational research

<table>
<thead>
<tr>
<th>How did we expand national, state and regional CTSA collaborations?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- UC Biomedical Research, Acceleration, Integration and Development (BRAID) workgroup metrics**</td>
</tr>
<tr>
<td>- Biobanking Program Evaluation*</td>
</tr>
<tr>
<td>- PSI/CTSI special project to bring pilot studies to multisite CTSA testing*</td>
</tr>
<tr>
<td><strong>Sample Evaluation Data Sources</strong></td>
</tr>
<tr>
<td>UC Biomedical Research, Acceleration, Integration and Development (BRAID) workgroup metrics**</td>
</tr>
</tbody>
</table>
- # and type of CTSA collaborations | Team |
- Criteria for success | |
- Performance dashboard | |

### Goal 2: Implement an Improvement Science Program with the intent of increasing efficiency, stimulating innovation and improving operational effectiveness in the CTSI and its community research centers.

In April/May 2012 we deployed the inaugural UCLA CTSI organizational effectiveness survey of 733 CTSI personnel, users and members; the response rate was 56% (n= 409). The Evaluation Self-Study reports survey results.

### 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 (see section d above).

### Goal 4: Collaborate with local, regional and the CTSA National Consortia and participate in the national process and outcome evaluations.

- **Dr. Davidson:** CTSI Evaluation KFC Cohort Presentation (9/2012), CTSI Evaluation F2F poster (10/2012), American Evaluation Association Annual Conference CTSI panel (10/2012), UC BRAID Metrics and Biobanking Repository workgroup member, UC BRAID annual retreat (9/2012).
- **Dr. Guerrero:** Evaluation and Education and Career Development KFC and Qualitative Methods Interest group member, American Evaluation Association Annual Conference CTSI panel (10/2012).
- **Dr. Inkelas:** Evaluation and Comparative Effectiveness Research Key Function Committees.
- **Dr. Kominski:** CTSI-Evaluation liaison CER and Community Engagement KFCs (11/2012).
- **Dr. Koniak-Griffin:** CTSI Nurse Scientist Special Interest Group, Council for Nurse Researchers (9/2012).

### f. Plans for Coming Year

In 2013, Evaluation will deploy the first UCLA Scientific Productivity Survey to track indicators of scientific productivity including grants awarded, number of publications, number of technology transfer items, and scientific/ health impact of the study. In 2012, the National CTSA Consortium proposed 10 key metrics for evaluation, including return on investment from pilot and K grants; number of technology transfer products; researcher and institutional collaboration; time from IRB submission to approval; studies meeting accrual goals; time to study opening; time to publication; influence of publication; and career development and trajectory. In 2013, we will work with the technology offices of the partner institutions to track technology transfer activity. If the proposed metrics selected for cross-site CTSA comparison, we will track them.

Additionally, our PI has emphasized the role of evaluation in testing and refining the new and emerging infrastructures and processes under development in the University of California Biomedical Research, Acceleration, Integration and Development (UC BRAID), a consortium of the five UC medical campuses with CTSAs. We plan to assess research infrastructure and improve protocols and processes to develop a seamless system for T1-T4 investigators to design and deploy research projects.

Other plans for the coming year are stated in the Evaluation Self-Study section.