a. Personnel

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

Co-leaders: Loretta Jones, MA; Ronald Anderson, PhD

Key personnel: W. Richard Brown, PhD; Daniel Castro, MD; Bowen Chung, MD, MSPH; Eric Daar, MD; Deborah Estrin, PhD; Susan Ettner, PhD; Craig Fox, PhD; Kimberly Gregory, MD, MPH; Calvin Hobel, MD; Moira Inkelas, PhD; Eli Ipp, MD; F. Javier Iribarren MSW, PsyD; Katherine Kahn, MD; Paul Koegel, PhD; Gerald Kominski, PhD; Michael Lu, MD, MPH; 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, consultant; David Zingmond, MD, PhD

b. Strategic Goals of the Program

<table>
<thead>
<tr>
<th>Yr.-1 Goals</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Establish community-investigator working group to update plan community</td>
<td>Completed</td>
</tr>
<tr>
<td>symposium, hold quarterly community conferences, and develop training for</td>
<td></td>
</tr>
<tr>
<td>community members and investigators</td>
<td></td>
</tr>
<tr>
<td>• Meetings with and survey of community partners</td>
<td>Nearly complete</td>
</tr>
<tr>
<td>• Hire and train CERP and HSR staff</td>
<td>Ongoing</td>
</tr>
<tr>
<td>• Establish working group on the role of Community Health Workers in</td>
<td>Completed</td>
</tr>
<tr>
<td>research</td>
<td></td>
</tr>
<tr>
<td>• Establish working groups with the LA County Department of Public Health</td>
<td>Completed</td>
</tr>
<tr>
<td>(Department of Health Services; Department of Public Health)</td>
<td></td>
</tr>
<tr>
<td>• Conduct place-based community assessments (e.g. 70 Block Project and</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Magnolia Place Project) that accelerate partnered research in diverse</td>
<td></td>
</tr>
<tr>
<td>communities</td>
<td></td>
</tr>
<tr>
<td>• Establish working group on novel study designs and analyses for</td>
<td>Ongoing</td>
</tr>
<tr>
<td>community partnered research</td>
<td></td>
</tr>
<tr>
<td>• Design partnered HSR protocols to identify/analyze datasets to inform</td>
<td>Ongoing</td>
</tr>
<tr>
<td>communities / investigators</td>
<td></td>
</tr>
<tr>
<td>• Identify and implement evidence-based interventions to improve health</td>
<td>Ongoing</td>
</tr>
<tr>
<td>care in community settings</td>
<td></td>
</tr>
<tr>
<td>• Establish CERP governance and operations structure, including leadership,</td>
<td>Nearly complete</td>
</tr>
<tr>
<td>working groups and conflict resolution procedures</td>
<td></td>
</tr>
</tbody>
</table>

c. Program Characteristics

Process

Drs. Brown (30% effort) and Norris (10% effort) have oversight of CERP. Ms. Jones (60% effort) shares many of the oversight responsibilities and is the principal architect of community-academic bridge-building conferences and of community and investigator training in CBPR. Drs. Shapiro (10% effort) and Andersen (10% effort) lead HSR activities in CERP. Our core is comprised of three major groups of participants: CERP community partners, CERP investigators, and HSR investigators. We hired a CERP Project Director who has over 10 years of experience in community engagement and health services research to oversee the day-to-day operations of CERP. She has two half-time FTE assistants. We have hired key community liaisons and research assistants and are interviewing candidates for additional community liaison coordinators, QI coordinators and a programmer analyst, in conjunction with Biostatistics Program (see BSD-CDM for details).

Progress

Opportunities in Implementing Relevant Program Activities

CERP investigators have led or partnered on more than 10 research proposals; four were funded and others are under review. We co-funded pilot investigator grants with the UCLA Resource Centers in Minority Aging Research, the CDU AXIS Center and Cancer Disparities Center.

Challenges in Implementing Relevant Program Activities
Identifying the research interests and priorities of community partners and investigators in the CERP. To address this need for information, we (1) surveyed our community partners; (2) plan to conduct a survey of academic investigators; (3) formed a working group between CTSI Programs (CERP, CCRR and Regulatory) and representatives of the SOM Dean’s Office, the Human Subjects Review Board and the Biomedical Library to develop a comprehensive inventory of community-engaged research that can assist CERP and CCRR in prioritizing use of limited resources to accelerate such research.

Administrative barriers to paying community agencies, which are full partners in research, yet due to university and NIH regulations, cannot be easily reimbursed for the important work that they do in the CTSI. We have been working with CDU, the UCLA Office of Contracts and Grants and the CTSI administration to resolve this issue.

Tracking new connections between and among CERP investigators and community partners. We are working with the CTSI Evaluation and Health Services Research Program (E/HSR) and the Biomedical Informatics Program (BIP) to develop a system that automates this process.

Modifications Made to Original Plan, Activities or Focus with Rationale
Dr. David Campa has left the Northeast Valley Health Corporation and can no longer participate. We are in the process of identifying two new community partners, to be selected by their peers, for leadership roles.

d. Major Accomplishments by Strategic Goal of the CERP Program

Goal 1: Promote and sustain bidirectional knowledge-sharing between community and academia.
CERP interviewed and surveyed community partners to characterize their clients, services, geographic areas, and priorities; and identify barriers to and facilitators of participation in research.
CERP has planned and sponsored the following, well-attended community-academic symposia (below) led by a highly qualified, multidisciplinary team of community partners and investigators (Jones, Wright, Koegel, Vargas, Chung, Ipp, and Daar). Community members, local agencies, and investigators were involved in all aspects of conference planning, contributed their expertise on the study panels, and attended as participants.

<table>
<thead>
<tr>
<th>Conference Title</th>
<th>Location</th>
<th>Attendees (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDU-UCLA Comprehensive Partnership to Reduce Cancer Disparities, “Prevention, Treatment and Control of Cancer in Our Community”</td>
<td>California Science Center</td>
<td>350</td>
</tr>
<tr>
<td>“Healthy Families: Protecting the Ties That Bind (A Close Look At Our Safety Nets)”</td>
<td>“ ”</td>
<td>283</td>
</tr>
<tr>
<td>“A Social Justice Model For Eliminating Health Disparities”</td>
<td>CDU</td>
<td>82</td>
</tr>
</tbody>
</table>

Goal 2: Strengthen community infrastructure for sustainable, partnered research.
Community Health Worker (CHW) Initiative. A group of investigators (Kahn, Irribarren, Chung) and community partners (Mission Community Hospital, HAAF, QueensCare) has formed to develop a framework for understanding the feasibility of using CHWs or promotoras to foster an infrastructure of community-based support services, align efforts between the health care delivery system and the public health system, serve as ambassadors to explain the research process, and work on research projects in roles that might include recruitment, retention, or data collection in collaboration the E/HSR and CCRR programs (See CCRR for more detail).

L.A. County Public Health Department Initiative. We have established two planning teams of investigators and public health officials: one with Drs. Katz and Yee of the Department of Health Services and a second with Drs. Kuo and Gonzalez of the Department of Public Health. The teams are working to plan the implementation and evaluation of initiatives to improve health outcomes for LA County residents through evidence-based prevention and management. We met with our community clinic and agency partners to discuss strategies for launching these model Community Centers in Health Education and Translational Research (CC-HEATRs).

Goal 3: Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.
The 70 Block Project team is developing a community-partnered approach to improve health outcomes by strengthening the built and social environments in Park Mesa Heights. The Magnolia Place Initiative is working with CERP investigators to use smartphone technology on two pilot projects: the first tests a parent texting network to improve health behaviors, and the second tests photovoice technology to increase social
connections and built environment improvements. The 70 Block and Magnolia Place project teams have held two joint meetings to share information on their programs and lessons learned.

CDU has implemented a **Community Faculty Track**, a novel and innovative pedagogic approach to academic-community partnership that recruits local resident community experts as university faculty members. A **Novel Study Design and Analysis Team** (Norris, Arab, D. Elashoff, Belin, Crespi, Sugar, and Liang) has been identified, to explore the use of practical or pragmatic trials to support high quality community focused research that enhances ethical and educational elements, while preserving the rigor of science.

**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 (1) disease burden within LA County, including “hotspots” of preventable illness, and (2) clinical, public health, and community resources in LA County that can be used to address these health needs.

**Goal 5: Establish a governance and operations structure that strengthens existing partnerships and builds new bridges between community and academia for research.**

We have held weekly meetings of the CERP/HSR leadership team and monthly meetings of CERP and HSR investigator teams to organize into working groups, review the composition of the CERP/HSR group, and make recommendations for involving new partners.

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

CERP investigators have participated in and presented at national CTSA KFC activities and workgroups and attended the National Community Engagement Conference, “Using IT to Improve Community Health.” Drs. Brown and Norris represent UCLA to the Community Engagement KFC and Dr. Norris is the voting member. Dr. Inkelas participates in the Outcomes of Community Engagement Workgroup. Locally, CERP faculty have initiated collaborations with our counterparts at the USC CTSI, including a joint USC-UCLA-LA County DMH fellowship for investigators to study, assess, and improve public mental health care (Braslow, Brekke).

**f. Plans for Coming Year**

- Sponsor at least four community-academic conferences.
- Advise affiliated organizations on community participation in scientific symposia.
- Refine and pilot test the Research 101 series of seminars / webinars for investigators and community.
- Partner with the Education Core to incorporate training on CBPR into courses for students and fellows.
- Analyze and interpret data from the community partner survey and use these data to inform CERP research priorities and efforts to reduce barriers to research participation in communities.
- Partner with the UCLA Dean’s Initiative on Community Engagement to conduct an investigator survey.
- Establish two community centers to support community engagement and research.
- Develop recommendations regarding the training, certification, and employment of CHWs in research.
- Establish a pilot funding mechanism to support sustainable partnered research in community
- Develop health system interventions and evaluations in collaboration with the LA County DHS and DPH.
- Pilot test CC-HEATR elements with two clinical partner organizations.
- The 70 Block Project and Magnolia Place Initiative will pilot community interventions with CERP faculty.
- Continued knowledge exchange between 70 Block and Magnolia Place initiatives to test and scale specific approaches to increasing bi-directional university-community partnered research.
- Refine and implement dynamic/adaptive/practical trial designs for community and clinical research projects.
- Advance Community Faculty Track at CDU and explore strategies to implement at other UCLA CTSI sites.
- Use findings from HSR analyses to characterize disease burden within L.A. County.
- In concert with CERP/HSR community partners, enlist disparate communities to engage residents, health professionals, and researchers in efforts to improve community health.
- Collaborate with community partners to design and conduct studies to identify and evaluate acceptable, feasible, and sustainable strategies to enhance community health.
- Quarterly working retreats to introduce community and academic partners to each other, refine the governance structure, launch working groups of community partners and investigators, and promote partnerships to achieve sustainable change in community health.
a. Personnel

Leaders: Christina Wang, MD; David Martins, MD, MS; Leslie Raffel, MD, MS; Isidro Salusky, MD

Co-leaders: W. David Hardy, MD; Eli Ipp, MD; Michael Irwin, MD; Carl Maida, PhD; Ronald Mitsuyasu, MD

Key personnel: Linda Burnes-Bolton, DrPH, RN; Loretta Jones, MA; Siegfried Rotmensch, MD; Lynne Smith, MD; Eric Kleerup, 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

Process

The CCRR has four Clinical and Translational Research Centers (CTRCs); outpatient units are located at UCLA Center for Health Sciences (CHS), Harbor-UCLA/LABiomed, Drew University, and Cedars-Sinai. Inpatient facilities are located at CHS and Harbor-UCLA/LABiomed. Program leaders have the following levels of effort: Dr. Salusky, 20%; Dr. Raffel, 25%; Dr. Martins, 15%; Dr. Wang, 40%. CTRC staff includes experienced research nurses, research dieticians, phlebotomists, clinical research coordinators, clinical nursing assistants, and recruitment specialists. Facilities available to aid investigators include two metabolic kitchens, two DEXA scanners for measurement of body composition, and two sleep study facilities.

Progress

Opportunities and Challenges in Implementing Relevant Program Activities

Our initial focus has been on maximizing coordination among the four CTRC sites and preparing for outreach activities into the community. To this end, some staffing modifications have occurred to assure that the sites have personnel who are able to function outside of a traditional clinical research center and to achieve alignment with increased outpatient vs. inpatient research activities.

The research nurses and dieticians have drafted standard operating procedures that are being implemented across all sites. This standardization began with the most commonly requested procedures, including vital signs, EKG, glucometer checks, phlebotomy, IV access and maintenance, specimen collection, processing of samples, measurement of height and weight, oral glucose tolerance testing, intravenous glucose tolerance testing, 300 mg carbohydrate diet, and medication administration. As time allows, the SOPs will be expanded to include less commonly performed procedures. An integrated list of available services has been developed and will be posted on the UCLA CTSI virtual home before the end of the grant year.

A liaison group was created to coordinate activities between the Community Engagement in Research Program (CERP) and CCRR. The liaison group has focused its attention on identifying initial studies in which to pilot CCRR/CERP collaboration. It tentatively selected two projects, the 70 Block Project and the Magnolia Place Project. The liaison group has initiated meetings between the CTSI and our community partners to define the ways we can work together to facilitate community-based research. During these meetings, it became clear that the model for using Community Health Workers (CHWs) or promotoras that was envisioned when the CTSI proposal was drafted will require revision.

We have made substantial progress in streamlining the implementation of research across the CTSI institutional partners. A common CTRC service application form has been developed. In conjunction with the Bioinformatics Program, discussion is underway on how best to integrate this common service application into the CTSI sites’ individual electronic submission process. Two sites have integrated CTRC service requests and scientific advisory committee review into the IRB application process, which provides efficiency for the investigator and the CTRC. Our goal is to expand this integration across all CTSI sites.
The IRB Harmonization Committee within the Regulatory Program has implemented a Reliance Review Model which allows investigators wishing to perform research activities 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. The Reliance Review Model minimizes duplicative IRB review. The Relying IRB(s) will generally accept the Reviewing IRB’s review, focusing only on a few local context issues when accepting the Reviewing IRB’s review. The Relying IRB does retain the right to reject the Reviewing IRB’s review and do its independent review upon rejection, but it is expected that this will be an infrequent occurrence. At present, scientific review and approval for CTRC support is occurring at each partner institution; the possibility of centralizing this process is under review.

During the transition from GCRC to CTSI, the CTRC’s have continued to provide support for our clinical and translational investigators—404 existing research projects continued to be performed without interruption and 79 new protocols were initiated, for a total of 4,799 outpatient visits and 210 inpatient stays.

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

As noted above, our discussions with CERP leaders and our community partners have resulted in a significant rethinking of the CHW service. The proposal included in the grant application called for hiring CHWs specifically to work for the CTSI. We now realize a better approach is likely to involve contracting with community organizations that have goals that dovetail with the focus of specific research projects. Many of these organizations already employ CHWs who have established relationships with the community. By partnering with these community organizations, it may be possible to take advantage of their expertise and standing within the community. CCRR, CERP and Evaluation and Health Services Research Program leadership has met and will continue to meet to develop a coordinated and functional CHW program that will effectively serve investigators and the communities. We envision the CHWs will participate in community-based research and aid investigators with recruitment and education and will explain the purpose of research and study procedures.

**Table 1. PI cost-sharing for new grants over duration of grant**

<table>
<thead>
<tr>
<th>Start date</th>
<th>5 yr.</th>
<th>4 yr.</th>
<th>3 yr.</th>
<th>2 yr.</th>
<th>1 yr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/12/12</td>
<td>23%</td>
<td>16%</td>
<td>11%</td>
<td>9%</td>
<td>6%</td>
</tr>
<tr>
<td>1/13/12/13</td>
<td>31%</td>
<td>27%</td>
<td>19%</td>
<td>14%</td>
<td>11%</td>
</tr>
<tr>
<td>1/14/12/14</td>
<td>39%</td>
<td>36%</td>
<td>32%</td>
<td>23%</td>
<td>16%</td>
</tr>
<tr>
<td>1/15/12/15</td>
<td>46%</td>
<td>45%</td>
<td>43%</td>
<td>39%</td>
<td>29%</td>
</tr>
<tr>
<td>1/16 on</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>

We recognize the critical importance of planning for the transition to an investigator cost-sharing model for CCRR services. Particularly in the current challenging fiscal climate, CCRR has an obligation to provide investigators with sufficient time to identify alternative sources to support aspects of their clinical research activities. The proposed model (Table 1 above) will gradually increase the percentage of research costs that investigators will be charged for all nursing and nutrition services, space charges, and hospitalization charges for inpatient units, allowing them time to include these costs into future grant applications. Once a study is funded, the cost-share agreement will remain unchanged during the funding cycle for that grant. (For grants funded before the model takes effect in September 2012, cost-sharing contributions will rise from 1% in January 2012 to 19% in January 2017.) This approach will achieve the goal of diminishing the proportion of costs borne by the CTRCs while providing investigators with the confidence that they can plan their studies without fear of sudden, unexpected changes in their costs of doing research. Dr. Kleerup, chairman of the UCLA-Westwood CTRC Operations Committee, designed our cost-sharing model. He joins the CCRR Program as a key personnel.

d. **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 staff have shifted the focus to outpatient research activities while continuing to support investigators who require inpatient services to perform their studies. The interaction with CERP and our community partners has prepared us to move into community-partnered research, with the expectation that our first projects will be initiated early in year 2.

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

The standardization of clinical research SOPs, development of an IRB Reliance Model, and the creation of a common CCRR application form will serve to make cross-institutional collaboration simpler and more straightforward. Discussions about a joint Clinical Research Core for Dentistry (CRCD) were initiated with the Weintraub Center for Reconstructive Biotechnology in the UCLA School of Dentistry.

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

The CCRR leadership meets regularly with junior faculty to provide guidance on how they can become involved in translational clinical research. Many CCRR leaders teach in various parts of the UCLA Graduate Training Program in Translational and Clinical Investigation and participate in the monthly face-to-face meeting of all trainees from all partner institutions, as well as in other CTSI educational activities. These activities often lead to individualized mentoring. In addition, a new pathway on clinical and translational medicine for medical students was initiated last year and a total of 50 students currently participate.

It is vital that we reach out to young people early in their education to make them aware of the importance and intellectual gratification that can come from a career in translational research. In addition to continuing our existing high school program with Long Beach Polytechnic High School, discussions have been initiated with Health Services Academy High School to explore ways in which the CCRR can interact with it.

e. CTSA Consortium, Activities and Contributions

Members of the CCRR leadership have been appointed to several of the CTSA KFCs, including the Clinical Research Management, Clinical Service Core, Community Engagement, and Regulatory KFCs. They participate in the KFC conference calls regularly.

**f. 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, a major focus will be on interactions with CERP investigators and our community partners. We plan to expand our educational activities to both introduce investigators to community-based research and to introduce our community partners to the types of research that is occurring within the CTSI. We will also initiate the Mobile Chaperone Service and implement the initiate CHW program with CERP.

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

Working with the Bioinformatics Program, we will work to facilitate investigator interactions via the virtual home. The facilitators in the Office of Investigator Services will aid in identifying investigators with complementary interests across the partner institutions, and we will assure that information about investigators and their research interests are listed on the virtual home and kept updated. We will continue working with the Regulatory and Bioinformatics programs to develop readily available forms that can be used to (1) identify the resources available across the CTSI, (2) gain study approval and (3) request services. This will serve to simplify cross-institution interactions and serve as the basis for harmonization of resource review and utilization across the partner institutions. We will work with the Translational Research Clusters (see Pilot Program) to identify ways in which CCRR can assist in developing collaborative research.

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

With the Office of Investigator Services, we will continue to offer assistance to young investigators entering into clinical research. We will institute a series of CTRC Open Houses to encourage trainees and investigators to visit the centers and learn about the resources available to assist them. We will team with our colleagues in the Education Program to introduce direct exposure to clinical research activities into training programs for students and young investigators as a means of expanding upon the didactic education they are receiving. Lastly, we will initiate training for research staff to assure that research is performed accurately and safely. These trainings will include collaboration with the Regulatory Program (for issues related to human subject protection) as well as programs led by our research nurses and dieticians on the correct way of performing specific research-related procedures.
a. Personnel

Leaders: Robert M. Elashoff, PhD; Steven Piantadosi, MD, PhD; David Elashoff, PhD; Andre Rogatko, PhD;
Co-leaders: Teresa Seeman, PhD; Magda Shaheen, MD, PhD; Peter Christenson, PhD; Roger Lewis, MD, PhD

Key personnel: Thomas Belin, PhD; Catherine Crespi, PhD; David Gjertson, PhD; Xiuling Guo, PhD; Steve Hovarth, PhD, ScD; Gang Li, PhD; Catherine Sugar, PhD; Hejing 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 consulting and CDM 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

Process

BSD-CDM Program leaders and members are situated at our four partner institutions: UCLA-Westwood, Cedars-Sinai, Harbor-UCLA, and Charles Drew University. Our leaders (R. Elashoff, 20% effort; S. Piantadosi, 5% effort; D. Elashoff, 15% effort; A. Rogatko, 25% effort) meet monthly and frequently communicate via e-mail and telephone. The leadership has focused on the activities of the budgeted staff, reviews of activity logs for all those receiving % salary support, availability of staff and the need to ensure the expertise necessary to carryout successfully projects. A major effort of the leaders is resource allocation and working through the problems of specific video conferencing at each of the four institutions. We have instituted training programs for faculty and staff in the utilization of technologies.

Staffing: 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. The additional PhD-level statisticians provide significant extra data analytic capacity. Dr. Liang has primarily been involved in supporting community research, Dr. Xiaoyan Wang has been involved with the pulmonary group in lung transplant follow-up and general statistical consults, and Dr. Chi-Hong Tseng has collaborated on a variety of clinical trials. We have hired a part-time administrative assistant.

The CTSI has assumed all statistical teaching and consulting activities for the SOM Dept. of Pediatrics. The Dept. of Pediatrics will support 50% of assistant professor Dr. Ning Li’s appointment in the SOM Dept. of Biomathematics. Dr. E. Landaw (MD, PhD), Chair of the Dept. of Biomathematics, is pediatrics-trained and will assist without CTSI support. These activities will also contribute to the CTSI Committee on Maternal, Child and Adolescent Health (MCAH).

Service Prioritization: Our CTSI currently has an open membership model. Accordingly, BSD-CDM in Yr.-1 provided consulting services based on the following criteria: (1) graduate students, medical students, fellows, and assistant professors without funding obtain sufficient support from the BSD-CDM to complete the project; (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.

Progress

Statistical Consulting: Exclusive of administration and special courses, the total statistical consulting hours contact hours with investigators at the four institutions was 3925 for the period July 1 2011 to Nov 1 2011. This was broken down as follows: 1834.2 hours for data analysis; 775.1 hours for study design; 541.1 hours in grant preparation assistance and 343.6 hours in data management. We have collaborated with 244 investigators on 260 projects. We assisted 44 fellows and students, 43 junior faculty and consulted on 3 projects that were joint collaborations with outside CTSI institutions.
The short time (four months) we had to develop and implement this BSD-CDM program was insufficient to produce manuscripts to be published based on the consulting that occurred during the time period.

Educational Activities: Introductory statistics courses were given by CTSI statisticians at Harbor-UCLA, Drew University, and at UCLA-Westwood. In addition, a grant writing workshop was given to pediatric fellows to teach about the construction of research design, sample size and statistics protocols. This workshop will be expanded out other departments and institutions in the next year.

Dr. Steven Piantadosi developed a national clinical research training program with lecturers and presenters from many parts of the country, including Los Angeles County. This week-long training section dealt with clinical trial design, grant development workshops and the complexities of clinical research. Dr. Piantadosi and his staff devoted hundred hours to designing this program and implementing their design.

Publicity: The program is publicized on the CTSI virtual home, by the leaders, and though the research facilitators. A major administrative effort especially by Drs. Robert Elashoff and David Elashoff was the presentation to all faculty and staff receiving CTSI support of the nature of the CTSI BSD-CDM program. This presentation was well-received. Additionally, we have identified and publicized initial points of contact for the BSD-CDM at each institution. The required statistical consulting is assigned to the appropriate faculty in consultation with site leaders (and program leaders in more complex cases).

d. Major Accomplishments

Goal 1: Provide coordinated, one-stop access to biostatistics consulting and CDM services.

BSD-CDM implemented “one-stop” statistical consulting during the four months covered by this report. We formed a collaboration with the SOM Dept. of Pediatrics; research is jointly supported. We also support the CTSI Clinical and Translational Research Centers (formerly the GCRCs) at the CTSI partner institutions. In an example of cross-institutional partnership and coordination, we have established working relationship between the UCLA-Westwood biostatistics team and the Hypertension Institute at Cedars.

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

We are completing our research on adaptive trials. We have focused on effects of amendments to protocol after the trial has been initiated and where the amendment deals with prognostic factors. Very few papers have studied this issue; we are doing so in collaboration with Dr. Karen Reckamp PI of a lung cancer clinical trial at City of Hope Medical Center. We do know that failure to handle this problem leads to biased estimates of treatment effects.

We completed two manuscripts that have now been accepted by Biometrika and Chest, respectively. The first deals with repeated measurement of biomarkers where a quantitative clinical endpoint is also repeatedly observed. There is 20–30% missing data and such data is nonignorable or ignorable in the statistical analysis. In the Chest paper the clinical outcome is repeatedly measured on an ordinal scale and prognostic factors are repeatedly observed. Again 20–30% of the data is missing and missingness is either nonignorable or ignorable in the statistical analysis. A different application of the methodology is for Dr. Saver’s stroke study. Previous research on this problem especially in the stroke literature has considerable misconceptions and modeling errors.

Our research in a new manuscript not yet completed examines the effects of nonignoreable, nonmonotone missing data on selecting prognostic factors. Both of these effects severely compromise variable selection; our work will be the first paper dealing with such effects. We have organized a team of statisticians under the chairmanship of Dr. Robert Elashoff and including Dr. Gang Li (UCLA), Dr. Ning Li (Cedars), Dr. Lin of Chengdu University in China, and Dr. Daniels of the University of Florida for this research program in the selection of prognostic factors.

High-throughput proteomic analysis. Our goal was to examine measurement and normalization techniques to reduce the experimental variation in data derived from a bead-based multiplex Luminex assay system which allows simultaneous measurements of proteins. The Luminex system has been increasing utilized at UCLA for translational research projects in a number of areas: lung cancer, lung transplantation, and rheumatoid arthritis. Normalization for the Luminex assay system requires a fundamentally different approach than the case of traditional high throughput data such as microarrays or protein MS. In the Luminex system, each
The experimental unit is a plate and each plate has results for multiple subjects and analytes. We quantified performance among different measurement systems (fluorescent intensity, background in fluorescent intensity, and observed concentration) and adapted various normalization techniques (scale normalization, quantile normalization, lowess curve normalization) to the Luminex data scenario and their performance was assessed across multiple datasets. Median and lowess normalizations appeared to result in reducing plate to plate variation the most.

The CTSA BSD-CDM has made contributions to methodology in community studies. Dr. Belin has developed alternative and novel randomization methods for community-based clinical trials and is applying this methodology to developing community trials. Dr. Catherine Crespi and Dr. Robert Elashoff are developing a community clinical trial with PI Dr. Ronald Victor at Cedar-Sinai that has as its goal the reduction of hypertension in African Americans using barbershops run by African Americans to recruit participants. The methodology is quite different from Dr. Victor’s Dallas study and will be included in a grant being developed for the February 2012 NIH grant deadline. Features of this methodology include the analysis of cluster randomized trials with repeated measurements, multiple outcomes, missed visits and the handling of non-normally distributed data.

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

Additional quantitative members have been recruited from the BSD-CDM program. New courses in grant writing have been organized and a more convenient statistical computer software JMP has replaced SAS (SAS is given as an elective by the Dept. of Biostatistics). We conducted our first video-conferenced Master of Science in Clinical Research statistics course and plan a second such course for the winter quarter.

e. CTSA Consortium Activities

We consulted other CTSAs before implementing the REDcap data management system. We are planning to attend the Biostatistics, Epidemiology and Research Design Key Function meeting in April, 2012. In addition, we have initiated collaborations with CTSAs at the University of Pennsylvania and the University of Florida.

f. Future Plans

**Goal 1: Provide coordinated, one-stop access to biostatistics consulting and CDM services.**

We will continue to advertise the availability of our services to enhance the BSD-CDM user base. This will include using the educational lectures as advertising vehicles. Additionally we plan to perform program evaluations. Our leadership will randomly choose several users and meet with them to discuss the quality of the consultation they received, including its strong and weak points, and whether they would use the service in the future. We will maintain our database of program users. We are recruiting and additional MS-level statistician who will be jointly supported by CERP. With the aforementioned addition of Dr. Liang, the future MS-level statistician will increase collaboration with CERP and development of specific methodology appropriate to community studies.

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

Future plans for high-throughput analysis: In addition to further work with network analysis methods and normalization/quantization strategies, one emerging trend is the use of multiple high throughput assessments (ex. miRNA, mRNA, proteins, metabolites) and our group plans to tackle the development of methodology to perform simultaneous analyses with these multiple data types. We have begun to develop network methods that combine the relationship between markers with sequence prediction results (ex. miRNA -> mRNA) to provide internal validation for the identification of important genes and pathways in translation research studies.

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

We plan to develop additional biostatistics short courses to be given across the four institutions. These will include basic statistics, study design, genomic statistics and clinical trials methodology. Additionally, we plan to increase the number didactic statistics courses available over video-conferencing.
Regulatory Knowledge and Support, Industry Relations and Research Program
Annual Progress Report (Yr-1)

a. Personnel
Leader: 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
Key personnel: Sharon K. Friend, MS; Marcia Smith BA; 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-wide “one-stop shop” for approval of CTSI-supported science.
Goal 3: Create an Office of Industry Alliances to promote and sustain the linkage of the CTSI, its members and industry partners.
Goal 4: 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 and is Director of the Office of Investigator Services (OIS). Dr. Laidlaw (5% effort) leads the continuing education program; Dr. Finder (5% effort) leads the ethics program; Dr. Eifaang (10% effort) leads the IRB harmonization work; and Dr. Mao (25% effort) directs the Post-Approval Research Oversight (PARO) and the Research Subject Advocate (RSA) programs. Dr. Mao replaced Dr. Roger Lewis as co-leader of the Regulatory Program; Dr. Lewis is a co-leader of the Biostatistics, Study Design and Clinical Data Management Program (BSD-CDM). Dr. Shaker-Irwin, a fulltime non-faculty administrator, is associate director of OIS and has oversight of the facilitation and PARO. Kathryn Atchison, DDS, MPH, has assumed new responsibilities at UCLA and is no longer involved in the Regulatory Program. We have recruited two research facilitators and two other facilitator positions are pending and we have hired an administrative assistant.

Progress
Opportunities in Implementing Relevant Program Activities (by Goal)
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.
The proposed changes in the "common rule" regulating research involving humans will facilitate progress in IRB harmonization and will accelerate the development of UC-wide, CTSI-wide and national reliance processes for multi-institutional research.
Goal 2: Develop pre- and post-approval regulatory support services through deployment of an Office of Investigator Services (OIS) and creation of a UCLA-wide “one-stop shop” for approval of CTSI-supported science.
We are in the process of integrating research activities among the partners including community members through the extensive utilization of domain experts as well as the full cadre of facilitators that have been recruited and identified. The RSA-PARO program has identified its role in research subject advocacy and on the ground constructive oversight of study execution. PARO harmonization between Cedars Sinai and LA Biomed has begun and will provide a template for full harmonization.
Goal 3: Create and Office of Industry Alliances (OIA) to promote and sustain the linkage of the CTSI, its members and industry partners.
UCLA-Westwood is in the process of completely revising its program related to industrial relations to markedly increase both the activity and yield. Cedars Sinai Medical Center, Los Angeles Biomedical Institute
at Harbor-UCLA Medical Center and Charles Drew University of Medicine and Science have functional and active programs for commercialization of research. Establishment of the enhanced program will facilitate greater cooperation.

**Goal 4: 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.**

Standardization of course offerings and storing course material for later use are beginning to make educational programs improved and more complete. The Research Ethics Committee is active and has a great opportunity to initiate the consultation program in concert with the national Ethics KFC.

**Challenges in Implementing Relevant Programs (by Goal)**

**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.**

National changes in research regulation including new PHS conflict of interest rules and revamping of IRB regulations have slowed the harmonization processes. We expect these to be resolved in the next year and, as they become clarified, to create new processes and policies that will prevent barriers.

**Goal 2: Develop pre- and post-approval regulatory support services through deployment of an Office of Investigator Services (OIS) and creation of a UCLA-wide “one-stop shop” for approval of CTSI-supported science.**

The Office for Investigator Services and the clinical and translational science support services are now active in serving investigators in the CTSI. In providing Regulatory Program services, we have been mindful of the nuances of community-partnered research. The participation of community partners has been bidirectional.

**Goal 4: 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.**

Some instructors must commute to teach at one another’s locations. We are working to increase our distance-learning offerings and train our instructors on distance-learning equipment to accomplish these goals. We are also planning to install equipment in community locations for both meetings and educational programs.

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

The Clinical and Community Research Resources Program (CCRR) is in the process of integrating a common Clinical and Translational Research Center (CTRC) service application form and Scientific Advisory Committee (SAC) review into the IRB application process. This “one-stop” procedure provides efficiency for the investigator and the CTRC. Moreover, the Center for Translational Technologies (CTT; see CTT Program) will issue RFAs for voucher funding for core resources that will be reviewed and prioritized by a Voucher Review Committee. Thus, there is no need for Regulatory Program to develop a “one-stop shop” for CTSI-supported science (see Goal 2). However, the Office of Investigator Services will continue to refer people seeking assistance with cores to CTT. The Office of Industrial Alliances (OIA) will be reorganized to align with changes in technology transfer at UCLA, Westwood. We are in the process of recruiting an individual to direct the OIA, which will initiate activities this year.

**d. Major Accomplishments by Goal**

**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.**

We have achieved a multi-institutional MOU for the IRBs at the CTSI partner institutions. The Reliance Review Model allows investigators who want to perform research activities 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. The Relying IRB(s) generally accept the review of the Reviewing IRB’s review. Thus, Reliance Review Model minimizes duplicative IRB review. We have nearly completed SOPs for this procedure.

**Goal 2: Develop pre- and post-approval regulatory support services through deployment of an Office of Investigator Services (OIS) and creation of a UCLA-wide “one-stop shop” for approval of CTSI-supported science.**
Our OIS started service in Yr.-1 and responded to 112 inquiries from June 1 through Nov. 30, 2011. More than 40% of inquiries required a simple answer to a question and 70% of inquiries took an hour or less to resolve. This early experience allowed us to determine the work requirements and time intensity for different kinds of questions. We are working with the CTSI Biomedical Informatics Program (BIP) and the Clinical and Community Research Resources Program (CCRR), which operates the CTRCs are our partner institutions, to develop an encounter document for use by all facilitators at all sites.

**Goal 4: 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.**

We identified and inventoried Responsible Conduct of Research (RCR) courses offered throughout the UCLA CTSI, and initiated a curriculum for continuing education of research team members and developed a course for investigators funded by NSF.

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

Program leaders participate in the Ethics and Regulatory key function committees and have participated in subcommittee meetings.

f. **Plans for Coming Year**

**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.**

We will complete the IRB database application for reliance. We will incorporate changes in the “common rule” into the harmonized IRB program. We will compile IRB time frame statistics to determine the role of IRB delays as a barrier to translational research progress and act on the findings to accelerate research approvals.

**Goal 2: Develop pre- and post-approval regulatory support services through deployment of an Office of Investigator Services (OIS) and creation of a UCLA-wide “one-stop shop” for approval of CTSI-supported science.**

Working with Biomedical Informatics Program (BIP), the OIS will develop and implement an online ticket for service requests that will allow us to efficiency provide and track services. The OIS will fill open additional research facilitator positions. The facilitator team will self-organize, identify CTSI resources to offer in response to inquiries and identify research barriers to address. The group will develop SOPs and identify needed areas of specialization. The RSA-PARO component of the OIS will inventory the IRB-related QA mechanisms and work to ensure that they are transparent to the partners for CTSI science. The RSA-PARO group will provide research oversight at the academic center research sites and work with CERP to develop mechanisms for providing oversight in community settings. They will initiate the development of efficient, constructive CTSI-wide research oversight processes.

As noted above, the CCRR Program will establish the “one-stop shop” for approval of CTSI-supported science.

**Goal 3: Create an Office of Industry Alliances to promote and sustain the linkage of the CTSI, its members and industry partners.**

As noted above, we are in the process of recruiting a director for this office who will facilitate collaborations to both increase and accelerate the commercialization of CTSI-wide inventions.

**Goal 4: 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.**

In collaboration with CCRR, we will conduct trainings for new clinical investigators related to human subject protection. We will initiate the consultation program at each partner and establish inter-institutional confidential consultations within the UCLA CTSI and nationally. We will hold meetings with an extended ethics interest group to develop proposals for research projects in ethics.
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

**Key Personnel:** Kathryn Atchison, DDS, MPH

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 through the Society of the CTSI.

**Goal 4:** Using a multidimensional recruitment strategy, recruit at least 25 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

**Process**

This program is managed by Dr. Leonard Rome, Senior Associate Dean for Research, 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 is provided by Dr. Rome’s office and the CTSI. Dr. Rome’s effort as well as the effort of his staff is 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.

**Progress**

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

The pilot program has a broad range of support vehicles that will be implemented in the first two years of the program. All of the grants programs will 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 first-year results are summarized here; for a complete list of pilots, please see our three-page pilot grant table, which immediately follows this section.)

In March, 2011 we awarded Clinical and Translational Seed Grants with institutional funds to three junior and two senior faculty. Upon receipt of a CTSA, we transitioned this program to the CTSI Scholar program using both NIH and institutional funds. After this one-year transition period, all CTSI Scholars will be junior faculty at the Assistant Professor level. The CTSI Scholar 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, we developed a Web-based online application, review and management software. This tool has allowed us to collect our first round of 23 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 two months. The Pilot
Program leadership is in the process of establishing a grants review oversight committee to analyze, rank and examine the grant reviews and make final funding decisions. The committee will include Program Co-Leaders from CDU, Harbor, and Cedars.

We also implemented the CTSI KL2 program using this same Web-based application tool. We selected three outstanding KL2 scholars from a pool of 28 applicants—10 from basic science, 11 from clinical research and seven from health services research (see CTSI-ED; Research Education, Training and Career Development Program for details).

The **Team Cluster Grant Program** supports multidisciplinary team-based research addressing major health problems in our community and will generate ideas and interventions that will lead to improved health. We successfully identified and leveraged four Team Cluster awards. Dr. Barbara Vickery is now leading a multidisciplinary study co-funded by CTSI entitled Systematic Use of Stoke Averting Interventions (SUSTAIN). Additionally, the CTSI awarded Team Cluster Grants to leverage Jonsson Comprehensive Cancer Center Transdisciplinary Grants to two teams comprised of three faculty members each. Lastly, we awarded a Team Cluster Grant to Dr. Joel Braslow to co-fund research related to a Translational Fellowship that integrates the efforts of UCLA, the Department of Mental Health and the USC CTSI.

We initiated **Catalyst Grants** to create interaction opportunities between basic and clinical faculty and community partners and to promote productive interdisciplinary collaborations, to sponsor a well-received seminar series focused on translational research, and to sponsor a dinner and lecture for our community partners focused on the non-fiction book, “The Immortal Life of Henrietta Lacks.” Many of our first round of grants went toward stimulating new interactions across the translational spectrum in areas of high impact in translational and clinical investigation.

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 this first year we supported one award to develop the Rapid Response Team (RRT) which will initiate, cultivate, nurture, support and enhance research and collaboration. Proof of Concept is being tested on the opportunities provided by and challenges of responding to Patient Centered Outcome Research (PCOR) initiatives which require rapid response to announcements with proposal preparation and submission in less than two months. Numerous new partnerships have already been forged, and a total of 18 applications were submitted to PCORI for the first single funding opportunity. Of particular value for grant oversight and evaluation purposes, the RRT software will generate specialized reports for PIs, administrative staff and other team members detailing status of grants and tasks, including Gantt charts, calendars, to do lists (see CTT; Center for Translational Technologies program for more details).

We awarded **Prototype Grants** to two faculty-student teams working on novel technologies through the UCLA Business of Science Center. One team is developing a nonaminogycoside compound that can read through nonsense mutations with the potential to induce large amounts of protein without the toxicity of aminogycoside compounds. The second team is developing a semi-automated vascular system for mouse models.

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.

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

We have not modified our original plan, focus or rationale.

**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 53 awards in our first year. These awards leveraged $738,000 in direct CTSI funding with $1.1 million in institutional matching.

**Goal 2: Develop novel clinical and translational technologies and methodologies.**
As noted above, we awarded an NTTM grant for RRT project development system, which fostered much new collaboration. Various CTSAs have expressed interest in learning more about our system and project management software.

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

The Society of the CTSI has been renamed the CTSI Scholar seed grant program. As noted above, we are in the process of evaluating 23 applications for 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. Five faculty received CTSI Scholar awards during our transition year.

Goal 4: Recruit at least 25 new CTSI translational research faculty over the next five years.

We have established a recruitment committee chaired by Dr. Gasson to identify promising translational scientists who will serve as catalysts for transdisciplinary collaboration. It reviews requests for joint recruitments from DGSOM department chairs and advises on recruitment strategies for high-impact areas in translational medicine. The committee meets February, June and October. It has successfully recruited its first new CTSI translational research faculty member, Dr. Jason Ernst.

e. CTSA Consortium, Activities and Contributions

We have teamed with the University of Southern California CTSI, as noted above, to support a Team Cluster Grant focused on mental health. Our leaders are in regular contact with leaders at the four other University of California campuses with CTSIs, a consortium known as UC Braid.

f. Plans for Coming Year

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

In the coming year we will announce a rolling application process for Catalyst Grants using our web-based application tool. As mentioned above, these grants create interaction opportunities between basic and clinical faculty to promote productive interdisciplinary collaborations around our six disease cluster areas. We feel that these grants have already been successful; however, we have not yet finalized the formal application process. For the first year of the grant they were managed ad hoc. By formalizing the process and advertising their availability on the CTSI Virtual Home, we will increase the promotion of transdisciplinary collaboration.

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

CTT identifies promising new clinical and translational technologies and methodologies and refers them to Pilot Program for consideration for an NTTM award. CTT anticipates soliciting applications for one new technology or method than has a high probability of being developed into a core. A CTT standing committee will score and prioritize applications (see CTT for more detail).

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

We expect to award a minimum of eight CTSI Scholar seed grants in 2012, as noted above. The Society of the CTSI has been renamed the CTSI Scholar seed grant program.

Goal 4: Recruit at least 25 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.
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**Roles and Responsibilities:**

- **Program Director/Principal Investigator:** Dubinett, Steven M.
- **End Date:** 7/1/2012
- **Date Range:** 6/30/2012
- **Location:** UCLA
- **Program:** Diversity Pipeline Initiative conference
- **Title:** UCLA CTSI/IMED Seminar Series

**Conference Details:**

- **Title:** UCLA CTSI/IMED Seminar Series
- **End Date:** 7/1/2012
- **Date Range:** 6/30/2012
- **Location:** UCLA

**Conference Objectives:**

- **Title:** Diversity Pipeline Initiative conference
- **End Date:** 7/1/2012
- **Date Range:** 6/30/2012
- **Location:** UCLA

**Conference Focus Areas:**

- **Title:** Diversity Pipeline Initiative conference
- **End Date:** 7/1/2012
- **Date Range:** 6/30/2012
- **Location:** UCLA

**Conference Highlights:**

- **Title:** Diversity Pipeline Initiative conference
- **End Date:** 7/1/2012
- **Date Range:** 6/30/2012
- **Location:** UCLA
The study compares the effects of different food sources of phosphorus.

**Training Program**

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**Project Objectives**

- Explore how some antibiotics may actually encourage spread of VRE by infection with VRE and explore how some antibiotics may actually encourage spread of VRE by infection with VRE.
- Assess the impact of antibiotic resistance on colonization and infection with VRE.
- Evaluate the role of antibiotic resistance in the pathogenesis of VRE.
- Evaluate the role of antibiotic resistance in the pathogenesis of VRE.
- Investigate the role of antibiotic resistance in the pathogenesis of VRE.
- Determine the role of antibiotic resistance in the pathogenesis of VRE.
- Assess the role of antibiotic resistance in the pathogenesis of VRE.
- Evaluate the role of antibiotic resistance in the pathogenesis of VRE.
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- Investigate the role of antibiotic resistance in the pathogenesis of VRE.
- Determine the role of antibiotic resistance in the pathogenesis of VRE.
- Assess the role of antibiotic resistance in the pathogenesis of VRE.
- Evaluate the role of antibiotic resistance in the pathogenesis of VRE.
- Investigate the role of antibiotic resistance in the pathogenesis of VRE.
- Determine the role of antibiotic resistance in the pathogenesis of VRE.
a. Personnel
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
Dr. Denny (25% effort) has overall responsibility for CTT. Assisting him are Drs. Rotter (10% effort), Filler (5% effort), Evans (5% effort), Vadgama (10% effort), Craft (3% effort), Svendsen (5% effort) and Teitell (5% effort). Dr. Svendsen replaces Dr. Pedro Lowenstein, who left the Cedars-Sinai Medical Center and therefore no longer participates in the CTSI. Donald Kohn, MD is no longer a CTT co-leader.

Progress
Opportunities and Challenges in Implementing Relevant Program Activities
• We created a searchable online database to connect translational researchers with core services.
In order to accurately evaluate and assess the depth of available core services within the UCLA CTSI, during the month of June and July site visits were held at all four campuses; these site visits allowed the CTT program director to directly survey TTR facilities on location, to update the TTR roster from the time of our initial submission in 2010 and to interview TTR core directors. As a result, a curated, up-to-date listing of TTRs has been generated composed of over 60 core facilities. TTRs were then parsed according to campus location and into one of eight functional categories. Working with the Bioinformatics Program, the UCLA CTSI Virtual Home was updated in late fall 2011 with this revised TTR data. Translational investigators can now browse for TTRs by either campus or category and get back accurate information regarding services provided, cost schedules and persons to contact. Though the CTT TTR site is now functional, it is anticipated that the TTR database will have to be periodically monitored and revised in order to stay current.

• We initiated a staged rollout of streamlined core access to CTSI clients through a voucher system.
The voucher system is a central feature of the CTT that empowers translational investigators to actively choose which core services will enhance their research. Because each partner CTSI institution was allocated a budget for vouchers in each of their subcontracts, and before we attempted to implement a system for the system-wide UCLA CTSI, we initiated a staged rollout using a more limited user population and set of TTRs. The first phase of this rollout, embedded in an RFA, was conducted at Cedars-Sinai, one of our four institutional partners. It was a resounding success (see section d., Goal 1 below). Before the end of year-1 we will roll out the voucher system at Los Angeles Biomedical Institute at Harbor-UCLA Medical Center and UCLA-Westwood, two other CTSI sites. What we learn from these RFAs will inform the launch of our CTSI-wide voucher system in year-2. The site-specific rollout process has been facilitated by a Technology Officer, who is advising individual investigators on networking and core utilization.

d. Major Accomplishments by Goal
Goal 1: Implement a system for providing centralized access to and ongoing performance monitoring of Translational Technology Resources (TTRs).
As noted above, the feasibility test of our voucher funding mechanism was well received. We received 80 applications in response to an RFA that was posted in early October, 2011 and publicized by e-mail and online. An expert panel of six reviewers evaluated and ranked the applications using a 1–5 scoring system and awarded vouchers worth up to $10,000 in core services, a total of $169,282, to 19 applicants (Table 1 below).

Table 1. Results of Year-1 Voucher Feasibility Test

<table>
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<tr>
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<td>Confocal</td>
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<td>Identifying Mechanisms of Immune Evasion in Glioblastoma Multiforme: TLR signaling and B7-H1</td>
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<td>Flow Cytometry</td>
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Goal 2: Create an efficient mechanism for developing promising technologies into functional TTRs.

- **CTT identified a need for a mechanism to cultivate, nurture and support research collaborations with particularly rapid “conception-to-submission” timelines and recommended development of a Rapid Response Team (RRT) to the Pilot and Collaborative Studies Program (Pilot Program).** The Pilot Program awarded Lenore Arab, PhD a “Novel Translational Technologies and Methodologies Award” to build project-development software for preparing and submitting grant applications and for fostering communication and collaboration among project team members. Dr. Arab piloted RRT in the fall of 2011 with the goal of fostering new collaborative teams from across the CTSI to compete for funding from the Patient-Centered Outcomes Research Institute (PCORI). This effort was a resounding success and resulted in 18 proposals from a total of 75 potential collaborators. (For more detail, see Pilot Program). We expect RRT will become a functioning TTR in year-2.

- **CTT has embarked on a cost-sharing strategy with the Shared Resources Consortium sponsored by the UCLA Chancellor’s office to jointly identify and develop translational technologies.** The Shared
Resources Consortium (SRC) identifies the need for new cores, evaluates core use and establishes procedures for sunsetting cores that are no longer in demand. The CTSI and other constituent groups at UCLA have created a pooled funding source to acquire, develop, maintain and sunset cores. By participating in this program, the CTSI can leverage its funding and achieve efficiencies in the oversight of cores. As part of this initiative, we have contributed from institutional funds $200,000 to the consortium and $100,000 specifically toward the purchase of a state-of-the art Illumina HiSeq 2000 sequencer, the first commercially available sequencer to i) enable 30-fold coverage of two human genomes in a single run for under $10,000 per genome and ii) perform gene expression profiling on 200 samples for under $200 per sample. The Illumina sequencer's NGS platform delivers up to 600 Gb of high-quality passing filter data per 2x100 bp run or up to 55 Gb of sequence data per day. CTSI representatives sit on the Shared Resources Consortium Oversight Committee.

**Goal 3:** Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs. Based on the successful Cedars-Sinai experience and voucher rollout endeavor, a CTSI-wide job description for a Technology Officer has been created and the job posted at the Center for Health Science at UCLA-Westwood, Harbor-UCLA, LA BioMed and the CDU campuses. We expect to fill this position before the end of year-1 so the officer is in place before our first CTSI-wide voucher RFA.

e. CTSA Consortium, Activities and Contributions. Dr. Denny has participated in monthly Translational Key Function Committee calls and is the UCLA CTSI's voting member to the KFC.

f. Plans for Coming Year

**Goal 1:** Implement a system for providing centralized access to and ongoing performance monitoring of Translational Technology Resources (TTRs). Based on the success of the Cedars-Sinai rollout already completed (see Table 1 above), we have developed a voucher RFA and online application and review system, which we plan to implement across the UCLA CTSI early in year-2. The schematic at right shows how the application and review process will operate. The key to this plan is that voucher funds will support resources proportionate to demand but not beyond.

**Goal 2:** Create an efficient mechanism for developing promising technologies into functional TTRs. As noted above, we have joined forces with the UCLA Shared Resources Consortium (SRC), which is tasked with developing, managing, coordinating and evaluating investment in core facilities for research activities. In addition, CTT identifies promising new clinical and translational technologies and methodologies and refers them to Pilot Program for consideration for an NTTM award (see Pilot Program for detail). CTT anticipates soliciting applications for one new technology or method than has a high probability of being developed into a core. A CTT standing committee will score and prioritize applications

**Goal 3:** Conduct personalized counseling and continuing education programs to facilitate collaboration and assist translational investigators in selection and optimal use of TTRs. As noted above, we will have two Technology Officers in place by the end of year-1 to provide personalized consulting services to CTSI investigators. The Technology Officers will serve as an intermediary between the Office of Investigator Services (see Regulatory Program) and directors of individual cores.
a. Personnel

**Leader:** Arthur Toga, PhD

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

**Key personnel:** Arash Naeim, MD, PhD; Alex Bui, PhD; Denise Aberle, MD; Robert Dennis, MD; Virginia McFerran, MD; Michael Swierink, MD

b. Strategic Goals of the Program

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<th>Dec</th>
<th>Jan</th>
<th>Feb</th>
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<td>RDR Organization and Education - Online survey</td>
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<td>2.2</td>
<td>Prototypes for RDR, including RDR services, CTS</td>
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<td>2.3</td>
<td>Navigate IRB issues (e.g. controlling access, data types, interface w Regulatory program)</td>
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<td>2.4</td>
<td>Registry of Research Databases -- CTSI-wide</td>
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<td>2.5</td>
<td>Define relationships among data sources at each partner institution including CareConnect, xDR, RDR, UC-ReX, other RDR integration efforts</td>
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<td>Analyze needs vs. functionality of design alternatives</td>
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<td>2.7</td>
<td>Architecture and Technology Design for RDR</td>
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<td>Develop RDR Strategy and Roadmap Report</td>
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<td>2.9</td>
<td>Prepare for and Design Clinical Trials Management System</td>
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<td><strong>Aim 3: Education and Training</strong></td>
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<td>3.1</td>
<td>Establish consultation services</td>
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<td>3.2</td>
<td>Plan workshops on CTSI infrastructure tools</td>
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<td>3.3</td>
<td>Plan Informatics training software seminars outside degree programs</td>
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<td>3.4</td>
<td>Plan new biomedical informatics course on domain ontologies, controlled vocabularies, data models, data curation, and clinical/biological data/text mining that draws in part on data repository experience</td>
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c. Program Characteristics

**Process**

Dr. Toga (35% effort) oversees all BIP activities and operations, assisted by Drs. Bell (30% effort), Fu (15% effort); Ogunyemi (15% effort); Taylor (15% effort); and Dworkin (5% effort). To help develop the software and other tools needed, we hired on a full- or part-time basis three programmers, an administrative analyst, a content producer, a systems administrator and a post-doc with informatics expertise.

The Institute for Informatics, a key element of BIP, is in the process of expanding its datacenter to a 1,100-square-foot space on the first floor of the Neuroscience Research Building. Construction is scheduled to be completed in April, 2012. It will house the Research Data Repository described above. This facility is being
outfitted with the latest high capacity datacenter standards, and will be able to support a 600kVA IT load when completed. The new datacenter will house five full racks of HP SL2x170z G6s, providing a total of 3,328 cores and 9.98 TB of memory for grid computing, and a rack of DL580 G7’s “fat nodes.” The datacenter will also house a 500 terabyte cluster storage system from Isilon. To tie the systems of the new data center together we will use networking technology from Juniper Networks. To insure security and HIPAA compliance, the datacenter will be monitored 24/7 with surveillance cameras, glass break sensors and biometric controls that include fingerprint and iris scanners to admit only authorized staff.

Progress

In order to ensure that BIP was responsive to the expectations of the other programs, meetings were held with each program area between 9/15/11 and 10/5/11. The program area leaders identified 73 “wish list” items and from that, a list of eight items was prioritized for Yr-1. A top priority was development of a UCLA “single sign-on” for all CTSI members whether or not they have a primary appointment at the Westwood campus (including all community partners).

The eight “top priority” systems developed or in development by BIP through Nov. 30, 2011 include:

- Single sign-on
- Ticketing system to track investigator, patient, community encounters.
- Vitae pages compatible with the VIVO ontology
- Development of Talent Pool associations based on Vitae pages
- Communications platform for announcements, events, funding opportunities, etc. (one-way communication)
- Communications platform for discussions, surveys (two-way communication)
- Virtual Learning Environment management system (Moodle platform).
- WISE, or Web-based Interactive Survey Environment, a tool using XML, Java and Javascript to administer online surveys.

d. Major Accomplishments by Goal

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

We have completely overhauled the back end of the Virtual Home, creating a custom content management system (CMS) to empower members to edit and control contact within their own programs. We created a membership database that is compatible with the VIVO ontology in order to be compatible with national initiatives. We carefully examined both VIVO and Harvard Catalyst/Profiles. We liked Harvard Profiles better but could not utilize a system built using a .net environment. Ours runs on a Linux for performance, security, and scalability reasons. The software we created and are now testing is Virtual Information Transcript Application Environment (VITAE). It is compatible with the VIVO ontology but extends some of the functionality to incorporate Facebook-like functions that control how and in what form communications are received. Access to the Virtual Home and VITAE will be provided using the UCLA single sign-on.

The Virtual Home has had 22,236 visits (as of 11/10/2011) from 124 countries/territories and more than 120 new member registration requests since it was launched in December, 2010. The “submit a question” feature has resulted in 71 unique queries, 55 were forwarded to Office of Investigator Services (see Regulatory Program), 15 were handled by BIP and one was forwarded to the Research Education, Training and Career Development program (CTSI-ED).

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).

Our effort to create and deploy a research data repository includes utilization of i2b2. As an aside, the five University of California institutions
with CTSA projects have created a consortium called UCRex to be used for sharing of data. We will utilize i2b2 and Shrine to link them in a federated model. The i2b2 construct has a variety of modules to further augment both data collection and interaction. We will be evaluating these modules as the system becomes more robust. The xDR is the conceptual architecture (see Fig. 1) for enterprise-wide set of activities to collect, organize and disseminate data. Fig. 2 shows the relationship between the RDR and the clinical systems from which data will be derived. We will enable controlled access to the RDR (after single sign-on authentication). IRB protocol approval and other factors will determine access. We have an agreement with the UCLA IRB to link our database with its protocol and approval database.

Goal 3: Provide training in informatics tools and methods.
The UCLA Training Curriculum Program (formerly the NCRR K30; see CTSI-ED) consists of three tracks. In Yr. 1, BIP (1) created a sequence of three, three-hour seminars for introductory Track 1, and (2) defined a Track 2 certificate program that presents focused informatics training. Track 1 seminars are Introduction to Biomedical Informatics; Data Standards & Terminology; and Practical Informatics Tools. They roll out in spring, 2012.

e. CTSA Consortium Activities
Drs. Toga and Bell attended the national Informatics Key Function Committee meeting in Rockville, MD in October, 2011 where we learned about the mature informatics activities of established CTSA.

f. Plans for Coming Year
Goal 1: Expand and amplify our established Internet portal (Virtual Home)
Program area leaders have identified a great need for an overall project/research management system. Such a system should integrate functions that allow investigators to request services, allow administrators to price and track usages of such services, and allow all members to manage research protocols. This is a high priority for Yr. 2. It is a policy of our CTSI to use or adapt software developed by other CTSA vs. building our own and we are working with the Evaluation and Health Services Research Program to identify available software. Accordingly, we have contacted the Medical University of South Carolina regarding their Services, Pricing and Applications for Research Centers (SPARC) system. While SPARC is a good prototype, it lacks some key features requested by UCLA CTSI program leaders. We have requested access to the SPARC source code when version 2 is released in January, 2012.

Goal 2: Establish a Research Data Repository, a Common Terminology Service (CTS) to support data harmonization and interoperability; and a Clinical Trials Management System (CTMS).
Our objectives for Yr. 2 are to complete prototypes for RDR and CTS and roll out RDR to UCLA Westwood and to CTSI institutional partner sites. (REDCap, was implemented in Yr. 1 at Charles Drew University of Medicine and Science and Los Angeles Biomedical Institute at Harbor UCLA Medical Center; it will be rolled out to UCLA Westwood and Cedars-Sinai.) We will monitor the observed vs. expected volume of patient data entering RDR from each CTSI site; volume of use statistics and user surveys; number of databases in registry; and number of databases facilitated by registry.

Goal 3: Train clinical and translational researchers and new biomedical informaticians.
We have commenced planning for the development of Track 2 of the Training Curriculum Program for informatics, leading to a certificate in clinical research. For Track 2, trainees complete six courses (and three Track I modules), some drawn from existing Master’s and PhD offerings. We aim to formalize this Track 2 program by June, 2012, with potential enrollees by September, 2012.
UCLA CTSI
Research Education, Training and Career Development (CTSI-ED)
Annual Progress Report (Yr-1)

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

b. Strategic Goals of the Program
Goal 1: Establish the CTSI-ED Office to optimize cross-disciplinary training and integrate community input into training into research activities throughout the CTSI.
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 (10% effort) directs the daily operations of the CTSI-ED Office with the assistance of Dr. Wong (20% effort), who directs the KL2 Program. Assisting them are co-leaders Drs. Devaskar (0% effort), Edelstein (5% effort), Fine (10% effort), Sun (10% 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 Curriculum Program (TCP; formerly the NCRR K30). Drs. Wilkerson (5% effort), Davidson (5% effort), Demer (7.5% effort) and Dipple (10% effort) complete the leadership. Lisa Chan joined CTSI-ED as the new senior administrative director effective Dec. 1, 2011. Ms. Chan has worked for Dr. Mangione for almost 10 years as the finance director of the Robert Wood Johnson Clinical Scholars Program and has wide-ranging knowledge of UCLA policies as they relate to training programs. She will liaison with CTSI senior administrative staff and with the TCP administrator.

Progress
Opportunities and Challenges in Implementing Relevant Program Activities
The CTSI-ED has established an office under the direction of Drs. Carol Mangione and Mitchell Wong (Goal 1). We addressed Goal 2 by creating the new KL2 Translational Science Award (previously referred to as the K12) and the new TL1 Translational Science Fellowship (previously referred to as the T32), directed by Dr. Ettner. We identified and awarded our four TL1 awards from a pool PhD candidates in the Department of Health Services at the UCLA School of Public Health. Each of these applicants has an outstanding academic record and research interests in areas that fit the type 2 translational research theme of the UCLA TL1. Additionally, they have strongly committed mentors who are receptive to adding CTSI mentors to each student’s multidisciplinary committee as needed to strengthen the science. We also awarded three KL2 awards from an outstanding pool of 28 candidates—10 from basic science, 11 from clinical research and seven from health services research. (Please see Trainee Progress Reports elsewhere in this report for more detail.) We created requests for proposals and an online submission process, and convened selection a committee. We currently are focusing on identifying the best community and academic mentors for our trainees and scholars.

Our KL2 Scholars are:

- **Amira Brown, MS, PhD** is an Assistant Professor and experimental neuropsychologist at UCLA who has recently accepted a faculty position at CDU. 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-
Joshua Zaritsky, MD, PhD is an Assistant Professor in Pediatric Nephrology at UCLA since 2008. The title of his project is “Hepcidin and the Anemia of Chronic Kidney Disease,” mentored by Drs. Isidro Salusky (UCLA Westwood); Tomas Ganz (UCLA Westwood); Kamyar Kalantar-Zadeh (UCLA Biomed).

Galareh Gabayan, MD, MSPH is a Visiting Assistant Professor at the West Los Angeles Veteran’s Administration, and Director of Quality Assurance for the West LA ED. The title of her project is “Patterns and Predictors of Poor Outcomes Following Emergency Department Discharge in Older Adults” and her mentors include Drs. Jerome Hoffman (UCLA) and Arthur Kellerman (Vice President, RAND Health).

Our TL1 fellows are:

- Erin Hahn was admitted to the doctoral program in 2009 and passed her comprehensive examinations in 2010. Her GPA is 3.81. She is currently working on a dissertation entitled, “Cancer Survivors and Survivorship Care.” Her dissertation chair is Dr. Patricia Ganz (UCLA Westwood) and the other members are Drs. Ron Hays, Mark Litwin, and Katherine Kahn. Ms. Hahn expects to defend her dissertation in the fall of 2012.

- Audrey Jones was admitted to the doctoral program in 2008 and passed her comprehensive examinations in 2009. Her GPA is 3.79. She is currently working on a dissertation using linked data from the National Health Interview Survey and Medical Expenditures Panel Survey to examine racial/ethnic differences in the mental health services and medical utilization and expenditures associated with new and chronic episodes of major depressive disorder. Her dissertation chair is Dr. Vickie Mays (UCLA Psychology and Public Health).

- Jenna Jones was admitted to the doctoral program in 2009 and took her comprehensive examinations in 2011. Her GPA is 3.75. She is interested in the formulation of policy solutions to address concerns with child and adolescent healthcare, for example racial/ethnic disparities and transitions from pediatric to adult care among children with special healthcare needs. She recently completed an analysis of how state mandates influence parental choices about vaccinating their daughters against the HPV virus. Her advisor is Dr. Nady Pourat (UCLA Public Health).

- Alice Villatoro was admitted to the doctoral program in 2008 and passed her comprehensive examinations in 2010. Her GPA is 3.85. Ms. Villatoro is interested in the correlation between perceived and actual mental health among Latinos and how this translates into treatment decisions. Her dissertation chair is Dr. Ninez Ponce (UCLA Public Health).

We have also begun planning for our TL1 Professional Student Program and an additional program for high school students. Dr. Cunningham is director of the Professional Student Program, which will pair 10 first-year students with senior research mentors, engage them in translational research, and provide a 2-month didactic program in interdisciplinary, community-partnered research during the summer. We have also begun planning our high school student program in which high school students from the Health Services Academy located in South Los Angeles will participate in a year-long program shadowing various health professionals in a clinical setting. The first cohort for both programs will be selected in the spring of 2012.

To achieve Goal 3, CTSI-ED Core leadership has worked closed with CTSI Bioinformatics Core (BIP) to identify the most robust platform for the CTSI Curriculum Tree as described in our application. After reviewing and considering multiple options, we have selected Moodle and will begin to develop the Curriculum Tree during January of 2012.
d. Major Accomplishments by Goal

Goal 1: Establish the CTSI-ED Office to optimize cross-disciplinary training and integrate community input into research activities throughout the CTSI.

As noted above, we have established and staffed the CTSI-ED Office. All administrative functions are either underway or being developed. Because of IT platform issues, in collaboration with the BIP, we have resolved these and will move forward with developing the “virtual” aspect of our plan.

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.

As noted above, we have started both the KL2 and TL1 programs and have identified seven outstanding translational scientists to train in these venues. In addition, we built on the strengths of our partner institutions to refresh and expand the centralized, broad-based CTSI TCP, which is directed by Dr. Salusky. New components include a clinical research curriculum for medical students; modules on community-engaged research, molecular medicine and systems biology; and workshops on statistical procedures applied to clinical investigation. We quadrupled to 12 from three the number of students in our Masters of Science in Clinical Research (MSCR) program.

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.

We have identified the most robust and flexible platform in collaboration with BIP and in collaboration with Pamela Davidson, co-leader of the E/HSR Program, we will begin to population the system with key translational science course work from the previously funded NCRR K30 program.

e. CTSA Consortium, Activities and Contributions

During the recently funded period, Drs. Mangione and Wong have been regular participants in the National KFC for the CTSA Education and Training Core directors. They have attended all regular monthly KFC webinars since Sept. 2011. They attended and presented at the face-to-face meeting of the California CTSA Consortium’s Education Division on Sept. 28, 2011 UCSD Faculty Club. The California CTSA Consortium includes the UC campuses with CTSAs and USC, Scripps and Stanford. Drs. Mangione and Wong will continue their active participation in both the national KFC and regional consortium.

f. Plans for Coming Year

Goal 1: Integrate community input and involvement into research training activities.

- Collaborate with the Community Engagement in Research Program (CERP) to reach out to the community and incorporate their participation in the CTSI-ED Core, our annual retreat and trainees’ research.
- Include community-based researchers as members of the mentorship team for each of our KL2 recipients.

Goal 2: Transform translational education

- Continue our KL2 and TL1 Programs, including the summer TL1 program for medical students.
- Expand our CTSI Training Curriculum Program (formerly the NCRR K30).
- Extend the highly successful UCLA STAR to UCLA CTSI partner institutions.
- Expand our programs for high school students including the Howard Hughes Medical Institute research program for disadvantaged students led by Drs. Marvin Marcus and Carl Maida.

Goal 3: Provide mechanisms to integrate patient-oriented research training through the CTSI Curriculum Tree

- Implement Moodle, an open-source software solution for our learning management system, starting with the CTSI Curriculum Tree.
- Expand access of the CTSI curriculum to trainees our partner institutions through our learning management system.
- Explore distant learning options for future expansion of training curriculum and improve access to courses and training across the four CTSI partnered institutions.
- Establish a place on the Virtual Home for the CTSI-ED Core and its training programs and curriculum.
Evaluation and Health Services Research Program (E/HSR)
Annual Progress Report (Yr-1)

a. Personnel

Leaders: Pamela Davidson, PhD; Martin Shapiro, MD, PhD
Co-leaders: Ronald Anderson, PhD; Moheb Bazargan, PhD; Moira Inkelas, PhD, MPH; Deborah Koniak-Griffin, RN, EdD; Loren Miller, MD, MPH; Jack Needleman, PhD, Michael Weisman, MD
Key personnel: Gerald Kominski, PhD; Kumar Rajaram, PhD, MBA; Ali Sayed, PhD

b. Strategic Goals of the Program

Goal 1: Longitudinally track and evaluate initiative and program outcomes.
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.
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 the CTSA national consortia and participate in the national process and outcome evaluations.

c. Program Characteristics

Process

The Evaluation/Health Services Research (E/HSR) program was organized by the four goals stated above and implemented by faculty and staff in Yr-1. The E/HSR program is led by Drs. Davidson and Shapiro. Dr. Davidson (40% effort) is responsible for oversight of all Evaluation aims, serves as the CTSA Evaluation KFC voting member, Evaluation Director of the Center for E/HSR, and co-chair of the CTSI Operations Committee. Dr. Martin Shapiro (20% effort) oversees all HSR aims, serves as the CTSA CER KFC voting member, and HSR Director for the Center for E/HSR. Three faculty serve as E/HSR leaders from the partner institutions: Drs. Mohsen Bazargan (5% effort) from Charles Drew University, Loren Miller (10% effort) from Harbor-LA Biomed, and Michael Weisman (10% effort) from Cedars Sinai Health System. Dr. Ronald Andersen (10% effort) serves as a Co-Director for the Center E/HSR. Drs. Inkelas (10% effort) and Needleman (5% effort) are responsible for developing the Improvement Sciences program (Goal 2). Dr. Deborah Koniak-Griffin (20% effort) is the E/HSR faculty assigned to the Community Engagement Program and its integration with CCRR. Dr. Gerald Kominski (5% effort) is E/HSR faculty for the Technology and CER RRT activities. Dr. Ali Sayed is collaborating to design a CTSI Education Program Management and Assessment System.

The Program employs four staff. Nicole Makowka assists the CTSI E/HSR monitoring committee and supports the program’s annual planning, implementation and reporting processes. Shanna Choi organizes the HSR faculty meetings and supports HSR co-leaders. Jim Morrison organizes and schedules the E/HSR program retreat and follow-up activities to develop the Center for E/HSR and develops the survey research function. Terry Nakazono, a programmer-analyst, conducts data analysis to analyze and report characteristics and needs of the diverse Los Angeles population by geographic area.

In Yr-1, E/HSR Faculty provided consultation to assigned components. We communicated with the CTSI Executive Oversight Committee (EOC), Operations Committee, and other program components via meetings, telecoms, videoconferences, and e-mail. In addition, the E/HSR Faculty and staff monitored integration and implementation opportunities and barriers of all UCLA CTSI partner institutions and components, and prepared the Self-Evaluation Report.

Progress

Opportunities and Challenges in Implementing Relevant Program Activities

E/HSR worked with leadership to design and implement a strategic planning effort to organize and launch the CTSI components and ensure alignment with the CTSA Consortium strategic goals and key function areas.

We conducted 38 meetings to engage our leaders in program planning, implementation, and formative evaluation. These included: five organizational meetings to craft a strategic planning process, three town hall meetings convened by Dr. Dubinett to orient leadership and investigators at our institutional partner sites on the CTSI overall and the critical role of evaluation, 19 component meetings with program leaders to advise
regarding the strategic planning process and to conduct implementation evaluation and select key metrics, six cross-functional program meetings were conducted to manage the interface, encourage integration among programs, and to select cross-functional, institutional level performance measures (e.g., BIP, CCRR, OIS, CERP), three EOC meetings (to orient on the strategic planning process, report results from the comprehensive program review, plan for implementing the transformative initiatives and evaluation plan in 2012), and two meetings convened by our program improvement team (BIP, CERP).

Our focus in Yr.-1 was on detecting challenges and barriers to program implementation and integration of activities across our four partner institutions and with community partners. All E/HSR faculty have assigned program monitoring responsibilities. Working with the CTSI leadership, we identified cross-cutting institutional priorities and initiatives. In December, 2011, we conducted a strategic planning retreat to implement the Center for Evaluation and Health Services Research (Goal 3). To streamline data collection, we worked with Administrative Core, which manages the CTSI-wide annual progress report.

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

Goal 2 involves the design and implementation of Improvement Sciences projects. This goal has been modified to apply improvement science methods to the CTSI. E/HSR faculty are focused on (1) the integration of the Clinical and Community Research Resources Program (CCRR) with the Community Engagement in Research Program (CERP); and (2) assessing CTSA-wide technology applications in collaboration with the Biomedical Informatics Program (BIP).

**d. Major Accomplishments by Goal**

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

- We convened individual meetings with the eight CTSI program area leaders to review their plans. We reviewed these plans with the CTSI Operations Committee and the Executive Oversight Committee (EOC). The planning process culminated in a comprehensive report on Aug 24, 2011 that focused on four elements: (1) extent of program alignment with mission and goals, (2) implementation and integration concerns/barriers, (3) an E/HSR research agenda, and (4) a summary of EOC recommendations.
- This process included 19 meetings with program leaders to discuss implementation and integration, selection of baseline metrics, and identification of high priority Yr-1 information/data systems components.

**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.**

- Dr. Moira Inkelas is working with the CERP and CCRR to identify and optimize alternative approaches to CCRR’s Community Health Worker/ Promotora program staffing plan and to develop aims/metrics (Please see the CCRR Progress Report for details.)
- Drs. Jack Needleman and Moira Inkelas are working with BIP to implement a strategy of assessing existing technology applications among CTSA in terms of open source and off-the-shelf applications. With BIP, they will provide recommendations on what needs to be built and what needs simply a user interface/integration strategy.

**Goal 3: Create the UCLA CTSI Center for Evaluation and Health Services Research (E/HSR) to accelerate the speed and efficiency of translational research for improving organizational effectiveness and population health.**

- We convened a planning retreat on Dec 3, 2011 attended by 61 members from four partner institutions, the Veterans Administration, RAND Corporation, the Los Angeles County Department of Health and Mission Community Hospital. The morning session was dedicated to: (1) reviewing Yr-1 accomplishments, (2) creating a vision for the ideal culture for institutional partner integration and collaboration, (3) assessing strategic opportunities and challenges, (4) brainstorming about how best to achieve CTSI impact through implementing cross-cutting transformative initiatives to demonstrate goal achievement, and (5) examining options for developing a self-sustaining E/HSR center.
- The afternoon session explored how E/HSR could (1) work through the CTSI to improve health in Los Angeles County, (2) identify a group of attainable short-term and longer-term goals, (3) move towards creating a center with which people want to affiliate, (4) organize E/HSR investigators to accomplish...
these goals, and (5) enhance cross-institutional collaboration. Dr. E. Richard Brown of the UCLA Center for Health Policy Research (UCLA CHPR) led a session with Dr. Patti Ganz, director of the Division of Cancer Prevention & Control Center Research at the Jonsson Comprehensive Cancer Center, to develop recommendations for core services and structures. The incoming director of the UCLA CHPR, Dr. Gerald Kominski, facilitated a small group discussion on stimulating collaboration. Next steps will involve an assessment of junior faculty needs, and plans for initiating and building the Center.

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

Dr. Davidson participated in the national CTSA Evaluation Key Function Committee (KFC) annual meeting (Oct 3-4, 2011); presented a poster session on, “UCLA CTSI Regional and Organizational Restructuring: Barriers and Opportunities in a Large Scale Change Effort.” Additionally, she served as a chair for the CTSA Panel sessions convened at the American Evaluation Association (AEA) Annual Conference, Nov 3, 2011, Anaheim, CA, “Values and Perspectives on Evaluating Clinical and Translational Science.” Dr. Shapiro participated on the CTSA Comparative Effectiveness Research KFC. Dr. Deborah Koniak-Griffin has been invited to join the Nurse Scientist Special Interest Group (NS-SIG) and we have nominated Dr. Inkelas to participate as the CTSA Evaluation KFC liaison to the Community Engagement KFC. Dr. Inkelas currently participates in the Outcomes in Community Engagement Workgroup.

e. CTSA Consortium, Activities and Contributions

In addition to activities in Goal 4 above, E/HSR faculty participated in eight CTSA Consortium meetings.

f. Plans for Coming Year

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

E/HSR will continue program monitoring and assessment of implementation and accomplishments to guide improvements. We will continue collaborating with the CTSI Operations Committee, Bioinfomatics, and all program components to design and implement the high priority data systems in Yr-2 starting with: (1) VITAE software (Virtual Information Transcript Application Environment) which is compatible with the VIVO ontology suggested by the CTSA Consortium and collectively agreed upon by the CTSA PIs, and (2) User tracking (see BIP and Self-Evaluation Report for details).

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.

E/HSR will continue its two improvement science priorities involving (1) identifying and optimizing alternative approaches to CCRR’s Community Health Worker program staffing plan and (2) assessing existing CTSA-wide technology applications that BIP can apply to our UCLA CTSI.

Goal 3: Create the UCLA CTSI E/HSR to accelerate the speed and efficiency of translational research for improving organizational effectiveness and population health.

In Yr-2 we plan to consolidate our analytic resources as part of the Center for E/HSR. To ensure integration, faculty from partner institutions will be an integral part of the infrastructure and leadership of the Center. We will develop a presence on the virtual home (VH). E/HSR faculty will begin to engage and train CTSI academic and community investigators. We will seek extramural funding to conduct evaluation and HSR studies to accelerate the translation process and to advance the science of evaluation.

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

- E/HSR faculty will continue the CTSA KFC participation (Evaluation, CER, Community Engagement)
- With UCSD Clinical and Translational Research Institute, we are planning to lead a UC Consortium initiative on CTSA Balanced Scorecard.