a. Evaluation Framework and Plan

The UCLA CTSI is a large-scale change initiative supported by the NCATS with substantial institutional support. Its four institutional partners are Cedars-Sinai Medical Center, Charles Drew University of Medicine and Science (CDU), Los Angeles Biomedical Institute at Harbor-UCLA Medical Center (LA Biomed) and UCLA-Westwood. The aims of the self-evaluation are to (1) document the transformation, (2) monitor progress against plan, and (3) investigate longitudinal impact. Our evaluation design is quasi-experimental trend analysis using mixed methods quantitative and qualitative data. At the California state level we are developing a multisite CTSA innovation platform and shared research infrastructure within the University of California, Biomedical Research, Acceleration, Integration & Development (UC BRAID). At the national level we are participating in the CTSA Evaluation KFC common clinical metrics and definitions initiative. In 2013, the proposed metrics will be vetted by the CTSA PIs and standard definitions will be prepared for collecting comparable data.

The sections below present each of the five CTSI institute goals, document the transformation in year 2, and provide a set of metrics we are monitoring at this developmental phase. The APR component reports, found elsewhere in this document, report progress against plan for each CTSI program component. The UCLA CTSI is still in the developmental phase. Future priorities and timelines for the CTSI and its evolution are the most critical factors that guide the direction, priorities, and evolution of the evaluation plan. For our purposes, evaluation is not conducted in isolation, rather it is an integrated, embedded function that develops parallel with the CTSI to (1) test innovation and novel approaches for building infrastructure and refining operating processes, (2) identify performance gaps so adjustments and improvements can be deployed, and (3) inform leadership decision making and utilize data-driven strategies to build and improve the CTSI.

a.1. CTSI Goal 1: Create an academic home for clinical and translational science.

The primary evaluation question for Goal 1 in the longitudinal evaluation is: How did we create and sustain an academic home for clinical and translational science? Meeting the Goal 1 vision will be accomplished through the activities focused on service excellence to accelerate scientific discovery.

Office of Investigator Services (OIS): The Regulatory Program’s OIS responded to 454 facilitation requests from Jan 1 through October 31, 2012. Table 1 below illustrates the range of investigator inquiries addressed by OIS facilitators. A pilot “ticketing system” to coordinate, track and measure satisfaction for CTSI services was implemented in fall 2012 for use in all CTSI programs. When fully deployed in year 3, this system will provide data for three of the proposed national CTSA metrics (i.e., volume of investigators, volume and type of services, and satisfaction/needs assessment). We will combine the data from the ticketing system with that collected by the OIS in years 1 and 2 to provide a continuous record of these metrics from the beginning of our grant cycle. This will allow us to measure progress over time as well as changing needs and/or satisfaction of our investigators with CTSI services. This information can then be used to provide rapid feedback to program areas and leadership to continuously improve performance.

<table>
<thead>
<tr>
<th>Request Categories</th>
<th>TOTAL</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Opportunities</td>
<td>146</td>
<td>22.60%</td>
</tr>
<tr>
<td>Human Research Consultation</td>
<td>143</td>
<td>22.14%</td>
</tr>
<tr>
<td>Regulatory Consultation</td>
<td>98</td>
<td>15.17%</td>
</tr>
<tr>
<td>General / Administrative</td>
<td>76</td>
<td>11.76%</td>
</tr>
<tr>
<td>Lab/Research Tech / Biospecimen Cores</td>
<td>41</td>
<td>6.35%</td>
</tr>
<tr>
<td>Education &amp; Training</td>
<td>38</td>
<td>5.88%</td>
</tr>
<tr>
<td>Collaborations with Experts (any field)</td>
<td>32</td>
<td>4.95%</td>
</tr>
<tr>
<td>Computing Resources / Informatics</td>
<td>27</td>
<td>4.18%</td>
</tr>
<tr>
<td>Stats / Study Design / Data Management</td>
<td>16</td>
<td>2.48%</td>
</tr>
<tr>
<td>Community-Based Collaborations</td>
<td>14</td>
<td>2.17%</td>
</tr>
<tr>
<td>Pre-Clinical / Translational Research Consults</td>
<td>12</td>
<td>1.86%</td>
</tr>
<tr>
<td>Evaluation / HSR</td>
<td>3</td>
<td>0.46%</td>
</tr>
</tbody>
</table>

Virtual Home: A leadership transition occurred in the Biomedical Informatics program (BIP). Dr. Arthur Toga was replaced by Dr. Douglas Bell in May 2012. The Virtual Home (VH) was replicated on a different server on
6/24/12 by Dr. Robert Dennis, director of Computing Technologies Research Lab (CTRL) and his team at the David Geffen School of Medicine (DGSOM). The VH is a central point of contact between the CTSI and many of its investigators. The flow of traffic is a tool for measuring which services are being utilized and what features may require revision. This traffic flow is being tracked via Google Analytics. In year 3, we will benchmark the CTSI VH traffic against comparable CTSA websites.

Clinical Translational Research Centers (CTRCs): CTRCs at our four sites have adopted common standard operating procedures and are in the process of standardizing application requirements for CTRC services. OIS and CCRR are working to actively promote CTRC services and develop new ones. Clinical and Community Research Resources Program is evaluating candidates for a Clinical Trials Management System (CTMS) which will allow for standardized tracking and reporting of costs, utilization and accrual at all four sites.

Organizational Effectiveness: In April/May 2012 we deployed the inaugural UCLA CTSI organizational effectiveness survey to assess and improve our responsiveness to investigator needs. We surveyed 733 CTSI personnel, users and members; the response rate was 56% (n= 409). Of those, 38% extremely benefited and 48% very much benefited from CTSI support. Perceived performance gaps included communication, collaboration and integration. In year 2, the CTSI organized the following outreach programs and events: (1) eight OIS facilitation consultations seminars, (2) town hall meeting at Cedars-Sinai Medical Center, (3) walk-in biostatistical consultations, (4)15 CTSI Presentations by Dr. Dubinett. The organizational effectiveness survey also provided an assessment of investigators needs for pre-proposal processes, clinical data, clinical trials, surveys and evaluation and HSR.

a.2. CTSI Goal 2: Build transdisciplinary research teams to accelerate and translate discovery.

The CTSI Goal 2 future state vision imagines a CTSA that builds high-performing translational science teams supported by relevant CTSI services, resources, and expertise.

Pilot and Collaborative Translational and Clinical Studies Program: In year 2, 87 awards were funded, co-funded or supported through institutional matching for a total of $2.3 million in direct CTSI funding, with $1.4 million in institutional matching. We continued support for the Rapid Response Team (RRT) to respond to Patient Centered Outcomes Research Institute (PCORI) initiatives and opportunities to meet the needs of investigators with preparation and submission times of two months or less. Two RRT-supported proposals received funding. “A Modified Delphi Approach to Defining a Patient-centered Community Health Center” (Robin Clarke, PI) received $307,985 from PCORI and “UCLA Alzheimer’s and Dementia Care: Comprehensive, Coordinated, Patient-centered” (David Reuben, PI) received $3.2 million from Centers for Medicare and Medicaid Services.

Center for Translational Technologies: In year 2, five core voucher RFAs were successfully conducted: Cedars-Sinai (1), LA Biomed (2), and UCLA-Westwood/CDU (2). A total of 384 applications were processed and 112 investigators (29%) were awarded vouchers in amounts ranging from $2,000 to $10,000, for a total of $1.05 million. Young investigators had a more favorable success rate (41%) than not-so-young investigators (22%).

Institutional Review Board Harmonization: In year 1, we instituted a Reliance-Review IRB process for CTSI collaborative projects. This allows the IRB of one institution (Relying IRB) to rely on the IRB of another institution (Reviewing IRB) for review and continuing oversight of human participant research. A revised MOU documenting the reliance review process was executed March 26, 2012. We subsequently developed and finalized instructions, forms for protocol submission, and a review procedure. A total of 12 protocols have been reviewed through October 2012.

Research Data Repository: UCLA launched its “xDR” Enterprise Data Warehouse project, with its initial top priority being the provision of de-identified clinical data for the University of California Research Exchange (UC-ReX) project, the first cross-campus clinical query system capable of exchanging patient-level data as well as aggregates (counts and descriptive statistics) across the five UC medical campuses with CTSA’s, as well as some of their key partner institutions. Initial population of data into the xDR and into UC-ReX is now nearly complete.

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

a.3. CTSI Goal 3: Transform educational and career development programs to promote the next generation of clinician investigators and translational scientists.

The primary Goal 3 evaluation question we will assess longitudinally is: How did the CTSI improve the quality, effectiveness and/or efficiency of research training and career development?

Research Education, Training and Career Development Program (CTSI-ED) is charged with conducting and coordinating clinical and translational science education for the UCLA CTSI. The CTSI-ED APR component report located elsewhere in this report contains details of the program achievements. The Evaluation Program documents the transformation, including implementation of the competency-based curriculum and mentoring services/satisfaction, and tracks trainees’ scientific productivity longitudinally. Given the EAB recommendation that evaluation of the training programs should be ongoing and allow adaptive re-allocation of training resources based on successes and identified gaps, the Evaluation Program developed standardized program evaluation surveys for the CTSI-Ed and adopted the Rockefeller University's Graduate Tracking Survey System (GTSS). The GTSS was recently featured in a CTSA Tool Shop Webinar (Dec. 7, 2012). The GTSS, a web-based electronic questionnaire pre-populates each graduate's information on publications, clinical trials, grants, and patents by downloading the information in standardized format from public databases, which simplifies completion for graduates, insures a uniform format of important information, and facilitates aggregation of data. The GTSS obtains information on whether trainees go on to improve human health, as well as related surrogate indicators of career development, and it is applicable to all training programs.

In addition, evaluation is a standing agenda item at all CREST Committee meetings, and the CTSI-ED leadership is using evaluation findings to improve the program. In year 2 for example, the Evaluation Program facilitated a competency mapping and curriculum review process for the Training Program in Translational Science (TPTS). This entailed having faculty within the TPTS to identify the NCATS Core Competencies in Clinical and Translational Research covered in their courses. The results showed a gap in meeting the bioinformatics competencies, and weaknesses in cultural diversity, leadership, cross disciplinary training and community engagement competencies. Subsequently, the TPTS Curriculum Committee used these results to propose new course offerings and to select a core set of competencies to be required of all UCLA CTSI trainees October 2012. Additionally, the Evaluation Program conducted a mentoring needs assessment in year 2. Interviews were conducted with research educational leaders from the four partner institutions (Guerrero 2012). The results revealed a lack of uniformity in how mentors and mentees were paired, how the mentors were being evaluated, and variability in the expectations set for these relationships. These results were shared with stakeholders, including the EOC. As a result, baseline and annual mentoring surveys for CTSI mentor/mentee pairs were developed with the CTSI-ED leaders and are being implemented in November 2012. In an effort to increase the overall number of K awardees among CTSI investigators, the CTSI-ED implemented its first UCLA CTSI K/Career Development Award Workshop (a workshop for junior investigators to learn more about how to successfully obtain a K award) on July 26, 2012 at UCLA. The goal of this workshop was to encourage the submission of K awards across the CTSI and to encourage junior investigators to consider a translational research focus. Over 60 postdoctoral trainees and junior faculty from across the partner institutions participated in this inaugural event. Evaluations from the participants noted an increase in knowledge in the components of the K award grant after attending. There are plans to offer this same workshop at each of the partner institutions in 2013.

a.4. CTSI Goal 4: Advance and expand strong bidirectional academic-community partnerships to ensure that new scientific discovery is relevant to community needs.

The future state vision is to build infrastructure that increases clinical research participation of knowledgeable, motivated community members and organizations that have extensive reach to Los Angeles populations.
Forging strong bidirectional academic-community partnerships is still in the developmental phase. Between year 1 and year 2, a 20% (N1=19; N2=27) increase was reported in the total number of community partners and a 16% (N1=43; N2=59) increase in the total research projects. Our year 2 evaluation report (1) emphasizes community infrastructure for conducting clinical and community-engaged research and (2) plans for developing the mechanisms for (a) matching academic researchers to relevant research infrastructure, (b) creating the pathways and processes that will facilitate seamless accrual of participants into studies, and (c) implementing and disseminating research to improve the quality and effectiveness of clinical practice and delivery systems.

In year 2, our primary evaluation question is: To what extent did the UCLA CTSI create a sustainable infrastructure for conducting community-partnered research? Several of the Community Engagement in Research Program (CERP) and Evaluation Program leaders drafted a working definition of “community infrastructure,” with four main elements:

1. The basic physical and organizational structures needed for the operation of the CTSA community-engaged research enterprise, and the services and facilities necessary for the operation to function.

2. The intellectual capacity needed for the operation of the CTSA community-engaged research enterprise, and the services and facilities necessary for the operation to function such as organizations, key stakeholders, and faculty.

3. These two core elements can be generally defined as the set of interconnected elements that provide the framework supporting an entire structure of development for conducting community engaged research.

4. Viewed functionally, research infrastructure facilitates the conceptualization and production of medical and health sciences research, and the implementation and dissemination of research results for improving delivery systems, clinical practice, and health impact.

a.5. CTSI Goal 5: Serve as a national resource for collaborative research through regional, statewide and national CTSA consortia.

A social network analysis (SNA), widely used among the CTSA to graphically present CTSA collaborations, is conducted once annually in the first quarter of each calendar year following APR. In early 2012 we conducted our first SNA, reporting 44 CTSA-level collaborations. Our next survey and analysis will be conducted in Jan-Feb 2013. In addition to building CTSA collaborations across the NCATS network, our future state vision is to co-create a regional laboratory for conducting translational research.

UC BRAID initiatives in 2012 include:

- **Biobanking and Global Informed Consent.** Our UC-BRAID proposal, “Engaging University of California Stakeholders for Biorepository Research,” received $2 million from NCATS to create an effective, efficient system for collecting and processing samples.

- **UC-Research eXchange (UC-ReX) Informatics Consortium** is building the first cross-campus clinical query system capable of exchanging patient-level data.

- **Contracting Working Group** is tasked with identifying policy changes, new infrastructure, standardized procedures or processes that will reduce the barriers to clinical research.

- **Drug and Device Discovery and Development (D4)** aims to leverage existing shared resources across the UC system to creative and innovative basic and clinical research at individual campuses, enable individual research, and create broad value in drug/device discovery.

- **The IRB Working Group** is identifying policy changes, new infrastructure, or processes that will reduce the barriers to IRB approval for the institution, individual researchers, and external partners.

b. Description of Milestones

The programs and initiatives of the UCLA CTSI are built around its five main goals. Evaluation collaborated with each program to develop implementation plans that summarize the specific aims, timelines, measurable objectives and milestones. Progress against plan is monitored by the evaluation and administrative offices with each program. Additionally, each program leader provides a biweekly update on progress and emerging initiatives, inviting input and suggestions from the leadership team. (A summary of goals, data sources, and metrics can be found in Table 1 of the Evaluation Program Progress Report.)
c. Future Timelines

**Goal 1: Create academic home.** In year 3, the Evaluation Program will use findings from the organizational effectiveness survey to conduct data-driven improvement planning with institutional partners and program components to improve the academic home.

**Goal 2: Build transdisciplinary research teams.** CTSI leadership will assess the viability and potential impact of several emerging initiatives with implications for evaluation: (1) University of California Center for Accelerated Innovation (application for NHLBI-funded, UC-wide center pending), (2) CTSI and the DGSOM Dean’s Office will collaborate to build a shared team science development office, (3) Survey of NIH, DOD, NSF top performers and high potential junior investigators, and (4) improve usability of RRT software.

As noted in the Evaluation Program report, we will conduct our first scientific productivity survey to evaluate the performance of translational science teams. Also as noted, the Evaluation Program will begin to track some metrics proposed by the national CTSA and is prepared to track all metrics adopted nationally.

**Goal 3: Education.** We will track the evaluation plans stated in the CTSI-ED component report, found elsewhere in this document. Additionally, we will analyze and report the results of the mentor/mentee surveys, and monitor the development, implementation, and improvement in the mentor program based on survey results. We will monitor the results of the initial GTSS and ensure the data are updated annually. In year 3, we will track the grant submissions and awards of K workshop attendees.

**Goal 4: Advance academic-community partnerships.** Evaluation will develop detailed plans for infrastructure assessment for funded and high priority emerging initiatives in the CTSI: (1) UC BRAID Biobanking Repository Education and Evaluation, (2) LA County Department of Health Services, (3) LA Data Repository. The infrastructure assessment results will be used by the CTSI in the developmental phase to design the interface between the T1-T4 investigators and the research infrastructure (e.g., settings, opportunities for translational research, standardized protocols and pathways to streamline regulatory requirements and research processes).

**Goal 5: CTSA collaboration.** In response to EAB suggestions we propose additional activities in 2013: (1) developmental evaluation of the UC BRAID Biobanking Repository pilot education program; and (2) develop a governance dashboard and select key metrics for success for attaining each of the five CTSI Institute level goals. We will select metrics that align regionally with the UC BRAID and nationally with the CTSA Consortium, in addition to those metrics adopted by the national CTSA for evaluation purposes across the consortium.