a. Conceptual Framework of the Evaluation Plan

We deploy a range of approaches to monitor and evaluate CTSI components and cross-cutting, transformative initiatives. These approaches include contextual, developmental, implementation, process/performance improvement monitoring, and summative evaluation.

Contextual evaluation assesses the policy, regulatory and industry environments as well as the characteristics of communities, universities, medical centers, providers, researchers and patients/population in the regional CTSI associated with clinical and translational research. Key contextual variables include: (1) the socio-demographic and health needs of our diverse Los Angeles communities; (2) the characteristics of our catchment areas and community research centers; and (3) the research expertise, resources, and services available in our CTSI to facilitate academic-community partnerships and research.

Developmental evaluation uses qualitative and quantitative data from the early phases of implementation to refine plans and to provide recommendations for improving structures and processes.

Implementation evaluation is tightly coupled with our annual strategic planning and is used to continuously monitor progress against plan.

Process and performance improvement monitoring examines the viability of innovative prototypes and the potential to spread effective improvement strategies [see Evaluation and Health Services Research (E/HSR) Program Report, Goal 2] using a mixed methods evaluation.

Summative evaluation uses longitudinal data to measure the impact of the cross-cutting, transformative initiatives over the CTSA grant cycle and demonstrate CTSI goal achievement.

Figure 1. UCLA CTSI Framework
Figure 1 shows the UCLA CTSI evaluation framework for improving organizational effectiveness and community health. The conceptual framework provides the rationale for our evaluation and is central to understanding the context, structures, transformative processes of our CTSI and defining the expected intermediate (organizational effectiveness) and longer-term (patient/community health improvement) outcomes.

**a.1. Description of Objectives**

Our self-evaluation is carried out by our E/HSR Program. The process has three objectives that are described in detail below.

**Objective 1: Develop an Evaluation and Tracking (E/T) System for monitoring progress and performance across the CTSI.**

In Year-1, we used a mixed “methods evaluation” approach that includes both qualitative and quantitative data. Semi-structured qualitative summaries of program progress were used to monitor implementation (see Implementation Reports discussion, Objective 2 below). We will use quantifiable indicators in trend analysis to monitor progress over time. We have drawn quantifiable measures from existing data sources, but newly constructed measures will be required for monitoring core program activities and operations in Years 1–2. We will include uniform measures suggested by the CTSA Evaluation KFC and Westat in addition to those unique to our UCLA CTSI.

E/HSR will prepare a data dictionary containing variable definitions and data formatted for each measure and metric. Program Area leaders in consultation with E/HSR faculty will agree on a uniform set of measures to be monitored across performance sites, programs, and community research centers. We will determine the appropriate time interval for collecting each variable and report longitudinal data to monitor progress against plan and trends. The quantifiable indicators will be collected via the Virtual Home for each CTSI program for both program management and evaluation and monitoring functions.

In this annual progress report (APR) a wide range of variables were reported by programs; for example, (i) the number and type of services utilized through the CTSI Office of Investigator Services (OIS), (ii) number of Biostatistics consultation hours, (iii) number of scholars/trainees and (iv) the number and type of pilot grants funded. (These variables are reported in greater detail in the individual component reports.)

In Year-1, technical support and expertise has been provided by Biomedical Informatics Program (BIP) to co-design the online E/T System that will be shared and integrated with other CTSI component reporting. BIP is integrating two software capabilities into the Virtual Home that will assist our information/data collection priorities: (1) VITAE; and (2) User and services tracking.

- **VITAE**: BIP is currently testing the 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. VITAE will serve as the foundation for all other CTSI/Virtual Home tools because it controls user access to read and write into the system. Using VITAE as the foundation, we will develop a phased approach for creating the E/T System in collaboration with the Executive Oversight Committee (EOC) and BIP. The strategy is to build on the Year-1 data reporting and expand that to collect 3-5 quantifiable indicators to longitudinally monitor each program’s activity that will most directly demonstrate CTSI impact over the grant period. As an illustration, the Biostatistics Program reported four-month activity that included 23 biostatisticians who collectively provided over 3,900 hours of consultation support. Currently this information is reported in a log by each statistician using Excel format. As soon as the VITAE system is operational, each statistician will record a uniform set of user information at the point of service. Ideally, we will work with BIP and Biostatistics to build in an automated reporting function to generate monthly, quarterly and annual progress reports. Additionally, we will build in periodic surveys to assess user satisfaction with Biostatistics services.

- **User and services tracking software (SPARC-like system)**: After meeting with CTSI Administration and relevant program area leaders (BIP, CCRR, Regulatory), it became evident there is a great need for an overall project/research management system. Such a system will (i) integrate functions that allow...
investigators to request services, (ii) allow administrators to price and track usages of such services, (iii) allow all users to manage research protocols, and (iv) allow administrators, program leaders and E/HSR to collect and analyze performance data. We have contacted the Medical University of South Carolina (MUSC) regarding their Services, Pricing and Applications for Research Centers (SPARC) system. While SPARC is a good prototype, it lacks some of the key features that are requested by UCLA CTSI program area leaders. As the system is built out, evaluation and tracking data will be an integrated component of this SPARC-like system.

Objective 2: Conduct implementation evaluation, provide ongoing progress reports and suggest high priority improvement initiatives.

Implementation Reports are based on the plans presented in the Implementation Phases and Milestones section (2010 CTSA submission). The E/HSR program ensures that the generation, quality and monitoring of implementation data to make certain all programmatic milestones are met. E/HSR conducted 19 meetings with all CTSI components to conduct detailed planning. These meetings often involved extended follow up by e-mail or phone. Program-area plans were vetted during weekly meetings with the CTSI Operations Committee and with the EOC. Each program review focused on three areas: (1) extent of program alignment with the CTSI mission and goals; (2) challenges and barriers to implementation and integration; and (3) the emerging agenda for evaluation/health services research (E/HSR). This process resulted in a comprehensive report and recommendations to the EOC in October 2011. Our recommendations are summarized below.

- Create a centralized workgroup to optimize planning, implementation and sequencing of priorities due to the broad scope of activities and the need for cross-program and cross-institution integration. This recommendation led to the creation of the Integrations Workgroup and a proposal to form cross-functional design teams to implement transformative initiatives (see Objective 3 below).
- Improve alignment between our Clinical and Community Research Resources Program (CCRR) and our Community Engagement in Research Program (CERP) to transition from inpatient to outpatient research. We realized a programmatic change and a cultural shift were necessary to achieve greater operational alignment. In response, E/HSR initiated an improvement project to help move these components to greater alignment and organizational effectiveness through CERP’s Community Health Worker Initiative (see CERP, CCRR for more detail).
- Identify and incorporate or build upon software developed by CTSA member institutions. The EOC endorsed this approach and “CTSA first” is now a standard operating principle at our CTSI.

Objective 3: Monitor implementation of five CTSI transformative initiatives to assess CTSI goal achievement.

Our CTSI has five overarching goals: (1) create an academic home for clinical and translational science; (2) build transdisciplinary research teams to accelerate and translate discovery; (3) transform educational and career development programs to promote the next generation of clinician investigators and translational scientists; (4) build and expand strong bi-directional academic-community partnerships; and (5) serve as a national resource for collaborative research.

In our 2010 submission, we identified five cross-cutting initiatives that we would use to assess achievement of our five CTSI goals. As part of our Year-1 self-evaluation process, our CTSI convened a strategic planning retreat on Dec. 3, 2011. We focused the brainstorming sessions on four elements: (1) identifying the highest impact initiatives to accomplish CTSI goals in 2011–2015; (2) proposing strategies to achieve each initiative; (3) identifying integration and implementation challenges and opportunities; and (4) identifying the resources required to implement the initiatives.

As a result of this process, we affirmed and updated the transformative initiatives from our 2010 submission. (see Highlights, Milestones and Challenges, Table 1 for the list of initiatives and additional details.) We presented the results of our “brainstorming” process to the EOC on Dec. 14, 2011.

In 2012 Dr. Dubinett will convene the first UCLA CTSI Annual Meeting. CTSI program design teams will form around each transformative initiative. Design teams will include cross representation of partner institutions, community representatives, relevant program components and E/HSR faculty and staff. When the teams start \[\text{Continuation Format Page}\]
meeting in early 2012, we will conduct detailed planning and present our evaluation design for each initiative, making sure we align with the evaluation logic models and uniform metrics promoted by the CTSA Evaluation KFC Workgroups.

a.2. Description of Milestones

The programs and initiatives of the CTSI are built around its five main goals (see Objective 3 above). E/HSR works with each program area to develop implementation plans that summarize the specific aims, timelines, measurable objectives and milestones. Depending on its complexity, a specific aim may involve between two to eight quantifiable milestones to be achieved over the five years of the grant. As noted in Objective 2, E/HSR tracks the timely achievement of milestones to evaluate each program’s progress and to recommend programmatic changes when necessary. The milestones for each program are listed in the 10-page Implementation Phases & Milestones section of our 2010 submission.

a.3. Description of Variables Measured and Types of Data Collected

As noted in Objective 1 above, a wide range of variables is collected. These include the number of: (1) consultations hours; (2) new collaborations formed; (3) funding proposals submitted and successfully funded; (4) new clinical and translational faculty recruited; (5) visits to the Virtual Home; (6) mentors trained; (7) new community partnerships established; (8) cross-institutional collaborations established; (9) new mentors recruited; (10) studies receiving clinical support; (11) publications arising for CTSI-supported research. Other variables include the accessibility of education courses and the quality of KL2 and TL1 applications. Individual program reports address these variables in more detail. Additionally, E/HSR conducts surveys to determine satisfaction with specific programs or services.

b. Human Subjects Protection

The UCLA CTSI places high importance on Human Subjects’ Protection (HSP) Programs, including privacy and confidentiality, at all partner institutions and within the community. Researchers conducting human subjects’ research are bound by the requirements of their respective institutions to be trained in human subjects’ research and to obtain IRB approval for their research. Two of our four partner institutions are accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The other two are in the application process. All protocols utilizing CTSI Community and Clinical Research Resources are required to have both IRB-approval and an approved data and safety monitoring plan.

Each partner has applicable requirements for HSP training. Most use the Collaborative Institutional Training Initiative (CITI) program that includes the required basic HSP training. In addition, this program includes a number of optional modules for good clinical practices, responsible conduct of research, and others which are also highly recommended for clinical researchers and other learner groups. We find that a number of our researchers choose on their own to take these optional modules.

As part of the requirements for participation in and funding from the CTSI training programs, trainees must complete courses in human subjects’ protection and a Responsible Conduct of Research (RCR) course. All trainees must also obtain and annually renew their IRB approval for their research and must submit documentation of their IRB approval to the training program director.

Confidentiality and privacy of research subject data are a priority. There are applicable HIPAA and data security training requirements at all our partners, as per federal, state and institutional mandates. All workforce personnel in clinical areas are required to satisfy this requirement.

Community partners are required to assure that their workforces have HSP training and IRB-approval prior to conducting human research. The Community Engagement program directs researchers to online HSP training and also provides seminars in community settings. The institutional partner IRB offices have been helpful in assuring that community based research is in accordance with all applicable regulations and respective Federal-Wide Assurances.

Institutional ethics training is required by many of our partners; this has direct applicability to properly conducting human subjects’ research. Our research ethics consultation programs within the CTSI infrastructure also contribute to assuring the ethical conduct of research.
The CTSI Facilitator and Post-Approval Research Oversight Programs (PARO) assist investigators and research teams with all human subjects’ questions that arise. More specifically, the Research Subject Advocate (RSA) Programs within PARO at our four institutional partners have over a decade of experience in assuring the safety and welfare of research subjects at their sites. This includes training, oversight, monitoring, safety reviews including adverse event reporting, and quality assurance. The RSAs are also directly responsive to any subject needs or concerns on a daily basis.

c. Summary of Findings

Our CTSI successfully launched key programs and advanced its goals in Year-1. Many of these achievements are outlined in the Highlights, Milestones and Challenges narrative and in the individual program-area progress reports. As noted above (see Objective 2), our self-evaluation process identified areas for improvement which have been or are being addressed. In addition, we have affirmed the transformative initiatives linked to our five CTSI goals and are creating design teams to accelerate these initiatives (see Objective 3 above and Highlights, Milestones and Challenges Table 1).

Many programs have identified the need for improvements or greater support and have taken action. These changes are reported in the program reports and include: (1) recruiting professional managers to oversee day-to-day program operations; (2) recruiting new faculty leaders to replace outgoing leaders; (3) instituting cost-sharing in recognition of fiscal realities; (4) allocating research study resources to the institutional partner best equipped to provide them; and (5) collaborating with other UCLA units to more efficiently use resources.

d. Future Timelines

In early 2012, we will participate in CTSI Annual Meeting planning. Administrators will organize cross-functional design teams to plan the transformative initiatives. E/T faculty and staff will participate in every initiative to develop and implement a parallel evaluation plan for monitoring the initiatives longitudinally to assess CTSI impact and goal achievement. We will continue to collaborate with BIP, the Operations Committee and all program components to design and fully implement the E/T System in Year-2.

e. Participation in the National CTSA

Our CTSI leadership has participated in numerous face-to-face and virtual meetings, webinars, conference calls and workgroups.

Steven Dubinett, MD, our Executive Director, regularly participates in monthly CTSA PI conference calls, monthly CTSA steering committee calls, and telephonic and face-to-face meetings of the University of California Biomedical Research, Acceleration, Integration & Development (UC Braid), a consortium of the five UC campuses with CTSAs that is developing a shared research infrastructure (see section f, Highlights, Milestones and Challenges for more detail). He attended the national CTSA Steering Committee face-to-face meeting Oct. 5–6, 2011 in Rockville, MD.

Associate Director John S. Adams, MD regularly participates in Public-Private Partnerships webinars, Executive Committee updates, CTSA PI conference calls and attended the 2011 Clinical and Translational Research and Education meeting.

Representatives of each program area and CTSI administration participate in all 14 CTSA Key Function Committees as voting members. In addition, program faculty leaders and CTSI administrators participated in the national CTSA KFC activities (e.g., monthly conference calls, annual symposia). Through participation in the national CTSC many local relationships have been initiated. For example, CERP faculty met with the leaders of the USC CTSA Community Engagement and Outreach Core to initiate discussions on collaboration. The UCLA CTSI participates in the California CTSA Education Consortium with the UC campuses with CTSAs, the University of Southern California and Stanford University.

As noted in our E/HSR Program report, Pamela Davidson, PhD, E/HSR leader, participated in the national CTSI Evaluation KFC annual meeting (Oct 3-4, 2011) and presented a poster on “UCLA CTSI Regional and Organizational Restructuring: Barriers and Opportunities in a Large Scale Change Effort.” She was a chair for CTSA Panel sessions at the American Evaluation Association (AEA) Annual Conference in Anaheim, CA in November, 2011. Martin Shapiro, MD, PhD, E/HSR leader, participates in the Comparative Effectiveness Research KFC.