

SUMMARY STATEMENT
(Privileged Communication)

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Application Number: 1 U54 RR031268-01A1

Principal Investigator

DUBINETT, STEVEN M MD

Applicant Organization: UNIVERSITY OF CALIFORNIA LOS ANGELES

Review Group: ZRR1 CR-3 (01)
National Center for Research Resources Special Emphasis Panel
CTSA II

Meeting Date: 02/22/2011
Council: MAY 2011
Requested Start: 07/01/2011

RFA/PA: RM10-001
PCC: CRT35

Dual IC(s): RM

Project Title: UCLA Clinical and Translational Science Institute

SRG Action: Impact/Priority Score: 14

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 1A-Both genders, scientifically acceptable

Minority: 1A-Minorities and non-minorities, scientifically acceptable

Children: 1A-Both Children and Adults, scientifically acceptable

Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	12,597,974	16,940,235
2	13,131,235	17,657,300
3	13,664,540	18,374,425
4	13,821,050	18,584,880
5	13,979,102	18,797,410
<hr/> TOTAL	<hr/> 67,193,901	<hr/> 90,354,250

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1U54RR031268-01A1 DUBINETT, STEVEN

RESUME AND SUMMARY OF DISCUSSION: This resubmitted application for an Institutional Clinical and Translational Science Award (U54) from the University of California Los Angeles (UCLA) entitled "UCLA Clinical and Translational Science Institute" requests \$67,193,901 in direct costs for five years including \$12,597,974 for Year 1. The structure of the CTSI includes UCLA, the Charles Drew University of Medicine and Science (CDU), the Los Angeles Biomedical Institute at Harbor UCLA Medical Center (Harbor-LA BioMed), and the Burns and Allen Research Institute at Cedars-Sinai Medical Center (Cedars-Sinai).

Strengths of this application include significance; approach; innovation; environment; implementation plans; CTSA staffing; governance; institutional commitment; local and national collaboration; data sharing; dissemination and evaluation plan; biomedical informatics; clinical research design and biostatistics; community engagement and research; participant and clinical research interactions; clinical research ethics; regulatory knowledge and support; translational technologies and resources, novel clinical and translational methodologies; and pilot and collaborative translational and clinical studies. Minor weaknesses exist in the research education, research training and research career development; research training record; institutional training environment and commitment to the program; recruitment, selection and retention of trainees and career development participants; and evaluation and tracking of research education, and research training and research career development.

This is a realistic and thoughtfully revised application that, through a recent needs assessment, focuses on training scientists in team science, matching resources to teams, and reducing regulatory burdens. There is strong engagement of both the academic faculty members and the community and consideration of cultural and economic determinants of health. A major change is the appointment of a new Principal Investigator who brings to the CTSI a fresh perspective as well as substantial expertise in leading major translational research programs. The descriptions of a reorganized governance structure that has appropriate representation from the four General Clinical Research Center (GCRCs), which are combining into the UCLA Clinical and Translational Science Institute (CTSI), reflect a comprehensive response to the prior review. There are new strategies to overcome barriers across multiple partner locations and a sound plan to involve community members in key steering committees. The focus on community engagement that holds potential for collaborations and improvements in community health is outstanding. There is significant institutional commitment.

Minor weaknesses are the complexity of the CTSI that will make oversight of the multiple partnering institutions challenging and the lack of clarity on how the existing stellar research environment will be leveraged to maximize productivity. Although the previous GCRC structure will serve as a foundation, there is little discussion of the need to include all four institutions. The lack of clarity in the plans to relieve the Principal Investigator of current responsibilities is a concern. Other weaknesses include the membership of the Executive Oversight Committee (EOC) that is limited to physicians and the lack of discussion on the exclusion of leadership representation from the School of Nursing and the School of Dentistry, which detracts from the stated multidisciplinary focus. Another weakness is the lack of discussion about equitable representation among the participating institutions, considering that the UCLA is the largest partner among the four institutions.

The investigators in the Biomedical Informatics Core have clear authority and capabilities and demonstrated leadership in clinical research informatics and translational bioinformatics. The aims for data warehousing, research networking, data security, and consultations are comprehensive and justified. The collaborations related to data-sharing infrastructure across and between University of California-affiliated institutions have potential impact across the state and regionally, which could serve as a model for other CTSAAs. Weaknesses include the lack of a process for users to initiate access to the bioinformatics expertise and services and a work scope that may be overambitious and without

established priorities. Another weakness is the unproven capability of the existing database of expertise profiles to mesh with emerging CTSA-wide research networking standards.

A significant revision is the substantial increase in support for the Biostatistics, Study Design and Clinical Data Management Program (BSD-CDM) that includes additional statisticians. The BSD-CDM is seen as transformative in integrating the biostatistical and data management activities of the partner institutions. Plans for adaptive clinical trials and for statistical revisions that reflect trial amendments and primary endpoint changes are innovative. Although a recent survey helped determine the future services of the BSD-CDM, the demand for these services is not clear and this is a weakness. Community engagement is a substantial strength of the application and includes community participation in governance, leadership groups and activities that promote equity in decision making. There is a realistic description of the challenges and approaches relevant to the Los Angeles area and a clear plan for resolving conflicts between the academic and community partners.

The authority and responsibility of the leadership positions for the Participant and Clinical Research Interactions, Clinical Research Ethics, and Regulatory Knowledge and Support functions are well matched. Plans for cross training of research support personnel across the participating institutions promote the maximum flexibility and capacity in protocol support. Human subject protocol applications and informed consent documents are harmonized across institutions and work is in progress on establishing cross-institutional acceptance of Institutional Review Board (IRB) reviews.

The Center for Translational Technologies (CTT), established to coordinate the numerous biomedical cores and erase boundaries between the four participating institutions, has strong leadership and an outstanding team of investigators on the CTT Steering Committee. The translational technologies are appropriate with special emphasis on stem cells, gene therapy, and bioimaging. A voucher program is in place to stimulate use of the technologies through Translational Technology Resources (TTRs) and there is a plan to track utilization and quality control performance. Weaknesses include the lack of information on additional commitments to translational technologies, and the limited descriptions of ongoing research to develop new technologies or plans to involve new investigators.

There is a strong and successful history of providing research training to clinicians and an innovative and institutional-supported program to foster translational components in the research of basic scientists. The T32 training program has a novel focus on community-engagement research and an adequate research training record, although most of the data is from the DGSOM and the records for trainees from the other institutions are not clear. The plans to build upon the experience of the existing K12 and T32 programs are sound but limiting the program eligibility to physicians is a weakness. It is unclear if partners other than UCLA will participate in the Specialty Training and Advanced Research (STAR) program or if trainees from other institutions will be supported. Although there are appropriate metrics for training evaluation, there are insufficient details on assessing the mentoring quality and no information on how the EAC will provide for monitoring or how the plan for post-graduate interviews with all program scholars will be implemented. Other correctable weaknesses include exactly who is eligible for admission to the various programs is not always clear and some programs appear to exclude disciplines; the issue of the preservation of protected time is not explicitly addressed.

Overall, the application received an Impact/Priority score of 14 and the committee recommended five years of support with the budget as requested.

DESCRIPTION (provided by applicant): The UCLA CTSI is an academic-clinical-community partnership designed to accelerate scientific discoveries and clinical breakthroughs to improve health in the most populous and diverse county in the United States. An ethnic, economic and cultural mosaic, Los Angeles County provides challenges for health and disease research that few counties replicate. Our mission is to create a borderless clinical and translational research institute that brings UCLA

innovations and resources to bear on the greatest health needs of Los Angeles. We are aligning our strengths to support clinical and translational science that is in full partnership with and responsive to the needs of our Los Angeles community. Our UCLA CTSI is bridging disciplinary and institutional boundaries to create transdisciplinary teams focused on the greatest opportunities as well as the greatest needs in our region. CTSA funding will accelerate our progress in achieving our transformative mission and allow the UCLA CTSI to make significant contributions to the goals of the national CTSA consortium. To accomplish our mission the UCLA CTSI has established five goals: 1) Create an academic home for clinical and translational science that integrates and builds on the many strengths of UCLA and its partners, 2) Build transdisciplinary research teams to accelerate and translate discovery to improve health, 3) Transform educational and career development programs to promote the next generation of clinician investigators and translational scientists, 4) Advance and expand strong bi-directional academic-community partnerships to ensure that new scientific discovery is relevant to community needs and, 5) Serve as a national resource for collaborative research through regional, statewide and national CTSA consortia. In transforming our research enterprise, the UCLA-CTSI is guided by core principles including team science, flexible research infrastructure and community engagement. The UCLA CTSI is built on a strong foundation of success in discovery, translational science, community engagement and health services research. Unique resources of the UCLA CTSI include close collaborations with world-leading centers, institutes, schools and programs with which we will co-fund and conduct our clinical and translational science. With institutional support in the pre-award period, the UCLA CTSI has taken significant strides to transform its approach to clinical and translational biomedical research. CTSA funding will accelerate our progress in achieving our transformative mission and allow the UCLA CTSI to make significant contributions to the goals of the national CTSA consortium.

PUBLIC HEALTH RELEVANCE (provided by applicant): Los Angeles County offers an ideal environment for developing effective translational strategies and faces challenges including subpopulations who are underrepresented in all phases of research. Further its fragmented health care systems require implementation, dissemination and diffusion research for scientific discovery to have a large social impact. As the US population becomes more diverse in the 21st Century, our experiences and successes will offer a model for health improvement nationwide.

CRITIQUE

CTSA Significance, Approach, Innovation, Environment and Implementation Plans

Significance

Strengths

- The UCLA CTSI brings together four academic institutions, clinical partners, and the community. The application shows a strong engagement of both the faculty members and community. This consideration of the cultural and economic determinants of health is a strength.
- The efforts to streamline collaborations across institutions include harmonization initiatives across IRBs.
- The proposed change in governance assures input with from broad areas and includes voting rights.
- There is an institutional commitment of \$73 million over five years and \$202 million in space commitments.
- The application is realistic in what it takes to integrate the work and there are plans for weekly executive committee meetings and weekly integration meetings.
- The application doubles the budget for biostatistics and provides increases in funding.

- The application is thoughtful and driven by a recent assessment that recognizes the need to reduce regulatory and paperwork burdens, train scientists in team science, and transform the institutions by using resources to match teams.
- The plans to streamline the CTSI include a Virtual Home and central laboratories as well as cross-training research staff.
- The initiation of a mobile chaperone service as well as a promotora program is interesting.

Weaknesses

- Less well developed in the application is the functioning of the six Translational Research Clusters (TRCs) in mental health, cardiovascular disease/stroke, cancer, HIV, addiction, and diabetes/obesity, and how these teams are structured to ensure true translational science, the governance of the teams, and the linkage to CTSA network.
- The integration beyond medicine is underdeveloped. The environment is rich, but it is unclear how other clinicians and nonclinicians will be involved in the CTSI.
- Some of the novel aspects of the application, such as community-based lay health workers and mobile chaperone services, are less developed and it is unclear how these aspects will be implemented and transform the institution.
- Doctorally-trained biomedical informatics core leadership is needed to achieve integration of CTSA tools including i2B2, REDCap, Honest Broker, and RDS.
- The reliance of Velos eResearch across the four sites is insufficiently described.

Innovation

Strengths

- This CTSA biostatistics methods core has the ability to make strong contributions in this area.

Weaknesses

- Creating another user-friendly Clinical Data Management system is not well justified; it is not clear why this CTSI would not integrate CTSA products into their system.
- Novel approaches to move discoveries into practices are underwhelming in the application.
- The application shares some novel ideas to engage the community but appears more about getting community participation in research via the mobile units; this assumes that distance is the primary barrier but data to support this view in this context is lacking.

Approach

Strengths

- The needs assessment conducted in 2010 defines the particular challenges that should be addressed. Training in team science, reducing regulatory and paperwork burden, and matching of resources are required. The application is clear on goals, for example, the IRB, that are consistent with the needs assessment.

Weaknesses

- How meeting these needs will provide new opportunities across the spectrum of clinical and translational science is less developed. How the focus on six TRCs will transform the entire institution is unknown.
- The application does not make completely clear how strengths are leveraged to maximize productivity. The challenge will be to demonstrate how the CTSI actually transforms an already stellar and rich research environment.
- The application is less clear on certain goals related to the needs assessment.

Environment

Strengths

- The revised application describes a new Principal Investigator, Steven Dubinett, M.D., who has been a faculty member at UCLA for 22 years and has led major translational research programs in lung cancer.
- The revised application integrates existing programs and broadens community outreach.
- Institutional commitment includes \$73 million over the next five years to transform research and \$202 million in space commitments.
- This is a science-rich context and the proposed transformative changes, if successfully implemented, should provide the new generation of science envisioned by the Funding Opportunity Announcement.

Weaknesses

- It will be a challenge to obtain complete integration across the four sites. Despite high-level commitment, strong leadership will be required across all institutions involved to make sure the goals are achieved.

Implementation Plans

Strengths

- The executive committee meets weekly with all programs and Associate Directors and holds weekly administrative integration meetings, either in person or by videoconference.

Weaknesses

- Although the goals are set, the milestones and measurable accomplishments are less well developed. Alternative approaches in the face of barriers are not discussed in detail.

Score for CTSA Significance, Approach, Innovation, Environment and Implementation Plans:

1

CTSA Staffing, Governance, Institutional Commitment, Local and National Collaboration, Data Sharing, Dissemination and Evaluation Plan

Investigators

Strengths

- The Principal Investigator, Dr. Dubinett, replaces the previous Principal Investigator who was a chairman of a pathology and laboratory medicine department. Fresh ideas and talent is a strength. Dr. Dubinett is Associate Vice Chancellor for Translational Science reporting to the Chancellor for the CTSI and Vice Chancellor of UCLA Medical Center and Dean of the UCLA David Geffen School of Medicine (DGSOM). Dr. Dubinett has been at UCLA since 1988 and has a long track record in lung cancer research, including serving as Principal Investigator of a Specialized Program of Research Excellence (SPORE) in lung cancer, a NCI early detection laboratory grant award, and a Department of Defense grant award that is a program project on lung cancer research. His R01 and R21 grant awards are ending prior to the start of the CTSI.
- Dr. Dubinett has done original translational science in the area of cyclooxygenase-2 (COX-2) inhibitors of inflammation that is associated with the genesis of lung cancer.
- Dr. Dubinett has more than 200 publications on lung cancer research and has mentored 14 career development awardees who continue in academic work. He has over 20 years of NIH translational research funding and was a member of the NCI Translational Research Working Group. Dr. Dubinett has been the Director of the Division of Pulmonary and Critical Care Medicine that is a key academic program in academic medical centers providing excellent training for administrative work.

- Dr. Dubinett participates in numerous state and national committees demonstrating talent for potential interactions with other CTSIs. He is a member of the Molecular Medicine Institute and California NanoSystems Institute. He is in charge of biomarkers and biospecimen utilization in the American College of Surgeons Oncology Group (ACOSOG) and American College of Radiology Imaging Network/National Lung Screening Trial (ACRIN/NLST) National Lung Screening Trial. He is on the editorial boards of five journals and serves as a member of a NIH Study Section. He is on the external advisory boards of SPOREs at Vanderbilt, the University of Colorado, and Emory Cancer Center. He has received the American Thoracic Society Scientific Recognition Award. He chaired the NIH Committee leading to the chronic obstructive pulmonary disease (COPD) and Lung Cancer Request for Applications.
- The Principal Investigator has responsibility for the entire CTSI including the budget and chairs the Executive Oversight Committee. He reports directly to the Chancellor and Dean.
- Eugene Washington M.D., M.Sc., Vice Chancellor for Medical Sciences and Dean of the DGSOM, was recruited from the University of California San Francisco (UCSF) where he chaired the Department of Obstetrics, Gynecology, and Reproductive Sciences and served as Vice Chancellor and received praise as being a considerate leader. Importantly, in his new role as Vice Chancellor at UCLA he has chosen Dr. Dubinett to run the CTSI and has been providing strong support. The Chancellor, Gene Block, Ph.D., is a psychologist with an interest in circadian rhythms and Dr. Dubinett reports to him from the Executive Oversight Committee (EOC).
- There are CTSI Associate Directors to help with communication and work on intra-CTSA activities and the inter-CTSI activities with other CTSIs. All are EOC voting members. John Adams, M.D., is an orthopedist and molecular biologist and the founding program director of the UCLA GCRC. Neal Halfon, M.D., will focus on pediatrics as UCLA is part of the NICHD-funded National Children's Study. Carol Mangione, M.D., will focus on health policy and minority affairs. Arthur Toga, Ph.D., has expertise in neuroimaging and will oversee bioinformatics. Antronette Yancey, M.D., is in health services and directs the Kaiser Permanente Center for Health Equity and will handle community engagement. An Administrator will be hired. The Committee meets weekly. There will be a representative of each of the nine functions on the EOC.

Weaknesses

- This is a complicated CTSI with four GCRCs combining into one entity and requiring considerable diligence in visiting the many sites to keep the personnel motivated and to provide the necessary oversight.
- It is not clear if the CTSI Director has given up a sufficient amount of research and educational duties to manage this enterprise. The eight-point plan is excellent but appears tentative and needs greater specificity, for example, reduction of advisory board and editorship activities. He will turn over only the divisional clinical activities to his second in command. The plan of 6.0 months with only 1.2 months on the CTSA grant award is insufficient.
- The CTSI Director is Principal Investigator of two, T32 grant awards that have a total of 12 postdoctoral positions and he will step down from one. The T32 grant awards are critical to train translational science investigators and having assurance that another principal investigator in clinical science will step in would be important.

CTSA Governance

Strengths

- The CTSI has an EOC led by the Principal Investigator and the Associate Directors. The Principal Investigator has overall governance with budgetary authority and leadership responsibility with other components of the system and outreach to other CTSIs.
- The EOC meets weekly and will provide an opportunity to discuss programs, resolve conflicts, and keep in touch.

- There is an IAC with the two Vice Chancellors chairing: Dr. Washington, and James Economou, M.D., Ph.D., Vice Chancellor for Research, and membership made up of various faculty members for each of five Specific Aims. This assures accountability and integration of components into a coherent program. This structure will allow for maximal attention of the senior leadership of the administration.
- There is a Virtual Home to facilitate communication and already accomplished is a harmonization of the IRB approval process for submission of forms and decisions by the ethics committees.
- A new Committee on Maternal Child and Adolescent Health is formulated in response to previous review comments and it has a voice on the EOC.
- There is an ISC chaired by the UCLA Chancellor and composed of the leaders of all four institutions. The ISC will provide counsel and direction to the Principal Investigator.
- An External Advisory Board will meet annually at the CTSI retreat and have a second video camera meeting.

Weaknesses

- The greatest challenge is to coordinate the CTSI activities among the participating institutions. There needs to be an oversight process and evaluation program that can ensure all entities are optimally knowledgeable about the CTSI.
- The previous GCRC structure should be a building block for the future and needs to be reviewed in regard to the science taking place at each site. There are four GCRCs being combined into one CTSA grant award but there is a lack of discussion of the need for all four and their past history is not described.
- The application does not state if the Principal Investigator is a member of the ISC.

Institutional Commitment

Strengths

- There is significant institutional support of salaries and support personnel for the EOC.
- The financial commitment to clinical and translational science is exceptional. The \$73 million total commitment includes \$14 million for team-based research and staffing; \$5 million for a research data repository; \$17.5 million for CTSI faculty recruitment and clinical trials data management; \$15 million from UCLA Healthcare for clinical research; \$10.5 million from Cedars-Sinai for bio-banking, faculty members, and research imaging; a Harbor-LA BioMed commitment for clinical trial support and research pilot funding; and \$3 million from CDU for faculty development and informatics.
- The space commitment of 56,000 square feet for the CTSI home is extraordinary. This is new space and not re-earmarked old space.
- There are four outpatient units with 20,000 square feet of new ambulatory space opening in January of 2011. There are two inpatient units with six beds at the UCLA Medical Center and Los Angeles County-supported beds at Harbor-LA BioMed located 25 miles away.
- There are plans for an exceptional Translational Research Grant Program to match by seven fold the annual CTSI contribution of \$425,000. The support will provide for symposia grants for seminars and day-long meetings, new technology industry collaborative grant awards, translational technology grant awards, pilot grant awards of \$30,000 each, and cluster grant awards focused on addiction, HIV, cancer, cardiovascular disease and stroke, diabetes and obesity, and mental illness.
- The exceptional letters of support are from integral institutions and potential community leaders and hospital organizations associated with UCLA.

Weaknesses

- The new funding that is overseen by the Principal Investigator is not specified.

- There are no maps and figures to illustrate the outpatient and inpatient facilities, what is old and what is new, and the distance from one to the other.
- An Office of Investigative Services is being established to provide one-stop “shopping”. There does seem to be considerable bureaucracy at the institution.

Local and National Collaboration, Data Sharing, and Dissemination

Strengths

- The entire Goal 5 is dedicated to serving as a national resource for collaborative research through regional, state, and national CTSA consortia.
- The CTSI is already participating with the University of Southern California and the University of California, Irvine, in the Greater Los Angeles CTSA Coalition, which provides for coordination on online training, sharing of core services and expertise, community engagement and outreach, and developing a pediatric clinical trials network. This interaction has led to curricular coordination and to collaborations on functional brain mapping in the NCRR Biomedical Informatics Research Network.
- The CTSI participates in the West Coast CTSA Consortium.
- The CTSI has joined the Sharing Partnership for Innovative Research in Translation (SPIRIT), which is the first virtual consortium on data sharing for the CTSA program, and the CTSI has an excellent description of the research data sharing and software sharing efforts.

Weaknesses

- None.

Evaluation Plan

Strengths

- UCLA has an ISC that will gather information and make an annual assessment of the CTSI leadership using a standardized uniform assessment tool to survey superiors, peers, subordinates, and clients. The ISC will review all materials gathered and generate an assessment of each leader.
- There is a strong subspecialty training program for academic careers. This program will support the ambitious plans to recruit 30 new translational research faculty members over the next five years using a \$12 million allotment from Vice Chancellor Washington.
- There is a CTSI Evaluation and Tracking Program that will monitor the progress of all nine programs and identify ongoing needs for resource allocation. The evaluation and training program will utilize web-based surveys to assess the need, availability and utilization of resources and to track satisfaction with CTSI programs and resources.

Weaknesses

- None.

Score for CTSA Staffing, Governance, Institutional Commitment, Local and National Collaboration, Data Sharing, Dissemination, and Evaluation Plan: 1

Additional Comments to Applicant: In terms of the Principal Investigator’s time commitment, preference would be for 50% effort on the grant award plus institutional support in form of endowed chair or other prescribed source of UCLA funds.

CTSA Biomedical Informatics

Investigators

Strengths

- There is a strong informatics team with demonstrated leadership in multiple informatics sub-domains including clinical research informatics and translational bioinformatics.
- There is a substantial record of funding and research and development that includes both basic and applied informatics science activities, as well as support for programmatic initiatives.
- There is an outstanding commitment of institutional resources, proving investigators with significant capabilities to effect transformational change relative to the informatics environment that is in place.
- There is a clear, well-formed leadership model with excellent institutional authority and ability to execute programmatic aims. This authority and capabilities have been shown through recent accomplishments in terms of establishing and enhancing the CTSI informatics platforms, tools and services.

Weaknesses

- There are no major weaknesses relative to the investigators, their authority, or access to resources.

Biomedical Informatics

Strengths

- The application demonstrates a thoughtful approach to project planning, requirements analysis, and cross-programmatic informatics integration.
- There is a comprehensive set of aims and objectives covering needs in the areas of data warehousing and secondary use, research networking, data security, and consultative services. These activities appear to be justified by end-user needs and a recognition of requirements related to national collaborative efforts.
- Plans related to data sharing infrastructure and pilots, especially across and between University of California-affiliated institutions, are both novel and likely to have significant statewide and regional impact. This type of collaboration should be a model for other CTSA and regions.
- Plans for ongoing program evaluation and optimization are forward thinking and likely to ensure continuous impact and success relative to the informatics efforts.
- The authority of program leadership both with the CTSI and at the institutional level is exemplary and should be a model for other CTSA organizations.
- There is excellent institutional support and clear high-level commitment to creating an informatics environment capable of catalyzing high-impact Common Terminology Service and discovery science, such as the formation of I2.
- The training programs spanning a variety of trainee types should ensure a steady stream of informatics-literate investigators and trainees, as well as informatics professionals.
- The ability to integrate CTSA and caBIG-generated tools, technologies, and standards is critical and likely to allow for immediate compatibility and interoperability with national CTSA collaborative efforts.
- The track record of engagement and collaboration with other CTSA demonstrates the ability to interact with and support team science activities.

Weaknesses

- There is no description of a process and/or mechanism for enabling end-users a front door to expertise and services. Such consultative services and portfolio management tools are critical to success in the type of complex environment created by a CTSA.
- The capability of an existing expertise database to work with emergent CTSA-wide research networking standards is unproven, and could present a challenge in terms of expertise profiling and research networking beyond institutional boundaries.

- The scope of activities may be too wide even with significant institutional support. It may be necessary for the team to engage in more thoughtful scope control and project prioritization activities.

Score for CTSA Biomedical Informatics: 1

CTSA Clinical Research Design and Biostatistics; Community Engagement and Research

Investigators

Strengths

- The proposed team is highly qualified.
- The revised application doubles the BSD-CDM budget and increases the Master's level statisticians and senior faculty members.
- The application adds three faculty members: Thomas Belin, Ph.D., Catherine Crespi, Ph.D., and Catherine Sugar, Ph.D., to extend community-based biostatistical expertise.
- The application describes four well-qualified leaders.

Weaknesses

- Four people are listed as implementing the CTSI biostatistics consulting services network. It is unclear who leads this group, how disagreements will be resolved, or how priorities will be set and resources managed.
- There is a highly variable level of effort for each of the four leaders, ranging from 0.6 to three months.
- Dr. Belin, Dr. Crespi, and Dr. Sugar, are each only listed at 10% level of effort.

Clinical Research Design and Biostatistics

Strengths

- The innovations in methodology are apparent. The CTSI has already made substantial documented progress towards becoming a leader in this domain. The UCLA CTSI seeks to develop novel statistical applications and methodologies to address the complexities of biological data and the unique requirements of community-based research. First, they will develop adaptive clinical trials, for example, phase IIB to phase 3, and statistical revisions due to trial amendments and changes of primary endpoints. Second, joint research will be conducted in genomics and proteomics, including novel biomarkers and their evaluation, bioinformatics, and clinical correlates.
- A recent survey helped shaped the direction of future offerings. Basic services to be offered include: 1) contemporary data analysis methodology consultation, implementation, and epidemiology expertise; 2) the best available CDM software; 3) study design and grant preparation assistance; and 4) bioinformatic data analysis. Advanced consulting services will be provided in clinical trial design, statistical genetics, genomics and proteomics to synthesize data; relating genomic and proteomic variables to physiologic and clinical endpoints; and elucidating the contribution of genomic and proteomic factors to treatment effects in clinical trials.
- The BSD-CDM will expand to meet the need for community studies and new methodologies in observational study design.
- The BSD-CDM will transform the currently isolated and fragmented biostatistics and data management services at UCLA and its partner institutions into an integrated organization that offers comprehensive services and eliminates unnecessary overlap and existing gaps in resources.

- The CTSI has a comprehensive program plan to provide such services and secure FTP to facilitate data sharing and to provide specific face-to face interactions.
- A strong M.S. in Clinical Research program is in place.
- The application provides greater detail about communication and cross-cultural training.

Weaknesses

- The extent to which videoconferencing and webcasting actually help connect people needing consultative services is unknown.
- Specified funds for non-CTSI statistical support are not explicit. It is unclear how priorities are set and what thresholds there are for help. Resources must be distributed in a transparent easily understood formula for people to buy into the model, and it is unclear if new investigators have funding for this purpose.
- How graduate students are supported is not clear.
- The community-based methods are not well defined.
- The recent survey to shape the direction of future offerings did not seem to capture the demand.
- How the M.S. in Clinical Research plays into translational research is not as well developed. The application training plans are underdeveloped in this area.
- Although there is experience with the M.S. in Clinical Research, satisfaction data with respect to distance learning is absent.

Community Engagement and Research

Strengths

- The community engagement section is a significant strength of the application. Community members are well integrated into the UCLA CTSI Community Engagement Research Program (CERP) governance structure, leadership groups and activities in a manner that should facilitate equity in decision making.
- The application provides a realistic delineation of the challenges and comprehensive approaches for dealing with the issues relevant in Los Angeles. The application demonstrates a good understanding of priorities and practical issues as well as motivational issues.
- The community-based organizations that are currently engaged are impressive in number, breadth of service delivered, and populations served.
- Concerns in the previous application have been addressed. A clear conflict resolution plan is in place to remedy disagreements between the academic and community partners. The number of partners has been expanded and resources made available. Appropriate incentives are in place for sustained participation. The revised application includes work with health services research to work on research priorities.
- The design of an Executive Master of Science degree program with a concentration in community translational research is a strength of the application.
- Shared resources for the Clinical and Community Research Resources will likely increase communication between the CTSI and the community.
- The application describes plans to conduct as many as six intensive community-university partner demonstration projects leading to patient-centered and community-feasible strategies for improving health.

Weaknesses

- The funding support for the six community demonstration projects is not defined.

Score for CTSA Clinical Research Design and Biostatistics; Community Engagement and Research: 1

CTSA Participant and Clinical Research Interactions; Clinical Research Ethics; Regulatory Knowledge and Support

Investigators

Strengths

- The proposed leaders have experience that is clearly appropriate to their responsibilities.
- The authority and responsibilities of leadership positions are appropriately aligned.
- There is a well-described training plan for the leadership positions.

Weaknesses

- None identified.

Participant and Clinical Interactions, and Ethics

Strengths

- The proposed CTSA structure will encourage appropriate diversity of research participants.
- The subject protection in clinical interactions is appropriately described.
- The proposed use of research chaperones together with mobile research units will help engage and maintain subjects in research protocols.
- The cross training of research support personnel across settings that include inpatient, outpatient and community, as well as across participating institutions, will maximize flexibility and capacity of protocol support.
- The training in the ethical conduct of research is included and extends to research on ethical issues such as the contextual effects on informed consent.
- Good Laboratory and Good Clinical Practice procedures will be employed and monitored.

Weaknesses

- None identified.

Regulatory Knowledge and Support

Strengths

- The regulatory program functionality has now completed harmonizing human subject protocol applications and informed consent documents across participating institutions.
- The processes are underway to establish cross-institutional acceptability of IRB reviews.
- The combination of research facilitators that are project specific with domain experts across projects and within specific regulatory areas of expertise will facilitate protocol development and regulatory approval.

Weaknesses

- None identified.

Score for CTSA Participant and Clinical Research Interactions; Clinical Research Ethics; Regulatory Knowledge and Support: 1

CTSA Translational Technologies and Resources; Novel Clinical and Translational Methodologies; Pilot and Collaborative Translational and Clinical Studies

Investigators

Strengths

- UCLA has established the CTT to coordinate more than 100 biomedical cores. The mission is to transform the academic-clinical-community partnership into a borderless institute. The CTT is key to erasing boundaries of the four participating institutions of the UCLA CTSI.
- The TTR will be coordinated through the Office of Investigator Services where the clinical scientist can access relevant core technologies. Translational Affinity Groups cover nanotechnologies, bioimaging, proteomics, gene expression, genetics, gene therapy, immunobiology, and molecular screening.
- The Institute of Molecular Medicine is cited as a multidisciplinary community of basic and clinical scientists.
- Christopher Denny, M.D., directs the Gene Expression Core of the Jonsson Comprehensive Cancer Center (CCC) and conducts research in pediatric sarcomas and serves as the co-director of a computer technology research laboratory that works on bioinformatics. Dr. Denny is ideally situated and trained to perform directorship of the CTT.
- The CTT steering committee oversees resource allocation, coordinates informatics needs with core technologies, develops long-term growth strategies, serves to achieve a public health interest, and directs two technology officers who will interface with the Office of Investigator Services.
- The CTT Steering Committee includes Donald Kohn, Ph.D., an expert in transplantation of genetically engineered hematopoietic stem cells; Jerome Rotter, M.D., an expert in GWAS and exome sequencing; Scott Filler, M.D., an expert in flow cytometry; Anthony Butch, Ph.D., an expert in biomarkers; Pedro Lowenstein, M.D., Ph.D., an expert in experimental gene therapeutics; Timothy Deming, Ph.D., an expert in the biological activity of biopolypeptides; and Michael Phelps, Ph.D., an expert in molecular imaging. Dr. Christopher Evans, Ph.D., Director of UCLA Brain Institute, also chairs the Chancellor's Biosciences Initiative that provides funding and organizational structure to the 100 biomedical cores. This is an outstanding team.
- The CTT is fully integrated with other CTSI key functions.

Weaknesses

- There is little information on the amount of time and effort that will be committed to the CTSI apart from what is already in place.

Translational Technologies and Resources

Strengths:

- UCLA has the expected academic high technologies with more emphasis on stem cells, gene therapy, and bioimaging compared to other academic medical centers. The plan to offer these technologies is appropriate, well planned and organized.

Weaknesses

- There was little mention of the pursuit of research to develop new translational technologies.

Development of Novel Clinical and Translational Methodologies

Strengths

- One example presented is the CARDiosphere-Derived autologous Stem Cells to Reverse ventricular dysfunction (CADUCEUS) Trial, a NHLBI-supported clinical trial of intracoronary delivery of cardiomyosphere-derived stem cells in patients with ischemic left ventricular dysfunction following a recent myocardial infarction.
- There is a plan to engage new CTSI investigators in the use of new technologies.

Weaknesses

- There is little mention of active research to develop new technologies or a plan to involve new investigators in this type of research.

Pilot and Collaborative Translational and Clinical Studies

Strengths

- There is a voucher program providing funds up to \$20,000 per year to stimulate use of TTRs, and in 17 months 26 vouchers for over \$100,000 were awarded. The TTRs will be funded proportional to the volume of service promised by the awarded vouchers.
- The evaluation and training will track utilization statistics and quality control performance metrics of each level-2 TTR on a biannual basis.
- There is evaluation of existing cores and plans to survey CTSI users to identify level-2 cores for TTR support. This support may be for instrument purchase, data analysis assistance for CTSI investigators, or other uses.

Weaknesses

- None.

Score for CTSA Translational Technologies and Resources; Novel Clinical and Translational Methodologies; Pilot and Collaborative Translational and Clinical Studies: 1

CTSA Training

Research Education, Research Training and Research Career Development

Strengths

- There is a strong history of providing research training to clinicians with documented success in intramural award programs and the K30 graduate training program curriculum.
- The concept of building on past successes, adapting and augmented existing programs based on lessons learned, using existing and highly successful pipeline programs, and bringing together leaders of several current programs within the CTSI to coordinate programs is sound.
- The new translational graduate training track in molecular medicine, designed to encourage basic science trainees to develop translational components in their programs and supported by institutional CTSI support, is innovative and evidence of a strong institutional commitment to translation.
- The involvement of other CTSI functions in the educational program is excellent.
- Training and support of community members in the new Executive Master of Public Health program is innovative and valuable.
- The inclusion of community input into training programs, and the overall emphasis of several programs on community engagement research, plays to a major strength of the overall CTSI in this area.
- The efforts to organize the plethora of existing courses at these institutions through the curriculum tree should improve efficiency and be a valuable resource for trainees.
- There are programs and curricula to address a wide range of learners and needs.

Weaknesses

- Regarding clinician investigators, the focus is primarily on physicians. For example, only physicians are eligible for the new K12 program, which detracts from the stated multidisciplinary focus of the program.

Research Education Component

Strengths:

- The leadership of the educational program is outstanding, starting with the Associate Director for Education.
- Appropriate time is available for the leadership to carry out their functions.

- The structure of the governance, which brings together leaders from within the CTSI and from affiliated programs, is well designed and should facilitate effectiveness.

Weaknesses

- The existing educational programs appear to be most developed at the UCLA DGSOM site, Mechanisms to ensure that all partners will have equal access to CTSI educational programs and whether those from outside the partner institutions are also eligible to participate need to be specified. Although external program recruitment is shown, no plans are provided.

Research Training Component (T32)

Strengths

- The focus of the T32 program on community-engaged research is innovative, will help fill an important gap, and the proposed introduction to professional students is excellent. Since degrees will be granted by the Department of Health Services within the School of Public Health, health services research is the only option for trainees, which is highly focused and a defensible choice.
- The proposed number of slots is sufficient to create a viable program.
- The proposed mentors and faculty are excellent.

Weaknesses

- There is insufficient clarity to delineate how this new program will be distinct from existing doctoral degree programs in the School of Public Health, which presumably also address health services and community-engaged research. This is a minor criticism, as this is potentially an important program that fits well within the goals of the CTSA program.

Research Training Record

Strengths

- Although an exhaustive table of data with the five current T32 programs is presented and primarily describes projects early in the translational research phase, the most applicable record of prior trainees appears to be the experience with the STAR Program and the K30 program, both of which have good outcomes. For example, since 2000, 28% of graduates have received an NIH grant award, although only two are R01 grant awards, and 75% are in academic environments.

Weaknesses

- Most of the data presented appears to be from programs at the UCLA DGSOM site and the record of trainees from the other sites is more difficult to discern.
- The research accomplishments of the STAR graduates are not provided.

Mentored Career Development (K12) and Research Program Design

Strengths

- The concept of bringing together all the institutional K12 and other similar programs within the CTSI mechanism is excellent and will considerably aid the trainees in finding the appropriate opportunities.
- There is a solid plan to build on the experience of the existing K12 and T32 programs to form the foundation for the new K12.

Weaknesses

- Only physicians are eligible for the K12 program despite the participation of faculty members from the School of Nursing.
- Details of the proposed program are lacking. Three tracks of curricula are available but there is no description of the requirements or the electives. There are few details on the degree options

or trainee requirements, and there is no description of the research experience, including the required outcomes of the experience, such as a thesis or manuscript.

- It is unclear how expansion of the current, highly successful intramural STAR program to other institutions will be supported. A number of questions remain, such as whether the additional institutional funds committed by the DGSOM will support trainees from other institutions, if there are any goals for program participation from each partner institution, or what is meant by the application reference to increased opportunities for NIH-funded institutional training programs.

Preceptors/Mentors

Strengths:

- There is an impressive pool of mentors available with an excellent track record of successful mentees such as shown in the list of K12 mentors.
- A strong program to provide mentor training and tools is proposed.

Weaknesses

- None.

Institutional Training Environment and Commitment to the Program

Strengths

- The richness of the educational environment at the partnering institutions is a real strength as is the strategy of bringing together the leaders of various programs related to clinical and translational research within the Research, Education, Training, and Career Development Program (CTSI-ED) oversight group.
- There are several examples of strong institutional commitment, including funding of the expansion of STAR program and slots for several of the pre-doctoral programs.

Weaknesses

- The issue of the preservation of protected time is not explicitly addressed.

Recruitment, Selection and Retention of Trainees and Career Development Participants

Strengths

- Based on participation in existing programs such as T32, STAR, K30, and that of the Robert Wood Johnson Foundation, there is a large pool of highly qualified physician and pre-doctoral candidates.
- The plan for the recruitment and retention of underrepresented minorities and their track record in this area is outstanding, as are plans for expanding pipeline programs in the public schools.

Weaknesses

- Exactly who is eligible for admission to the various programs is not always clear and some programs appear to exclude disciplines. For example, the description of the evaluation of trainee recruitment mentions that the pool of applicants for CTSI-ED programs will be drawn from the four partners and the other six UCLA professional schools. Apparently, however, only physicians are eligible for the K12 program and there is no indication if or how students at these other professional schools will be recruited.
- The availability of candidates from other clinical disciplines is not clear.

Evaluation and Tracking of Research Education, Research Training and Research Career Development

Strengths

- The assessment and outcomes subcommittee is well configured to accomplish this task.
- The constructs to be measured are appropriate.

- The plan to adapt the institutional evaluation system for CTSI purposes is sound.

Weaknesses

- There are insufficient details on how the quality of mentoring will be assessed.
- There are no details about accomplishing the plan to interview all scholars from all affiliated programs at intervals up to 10 years after graduation.
- There is no information on how the EAC will provide monitoring or feedback to the educational program.

Score for CTSA Training: 2

Training in the Responsible Conduct of Research

Acceptable

Recruitment and Retention Plan to Enhance Diversity

Acceptable

CTSA Integration and Overall

Critique 1

Integration

Strengths

- In response to the prior review, the new plans to overcome barriers to integration across multiple locations by several means, including reorganization of governance, are promising. The proposed structures of the already-operational Oversight Committee and the CTSI office, and the use of Associate Directors, should effectively involve all partners and leaders of key functions in the decision-making process.
- There is already a track record of the CTSI interacting with existing CTSA's, both in the region and elsewhere, and a robust plan to build on these interactions through developing shared infrastructure.
- The new governance plan that is revised based on prior reviews includes appropriate representation from involved partners and also has excellent strategies for involvement of community members in key steering committees.
- If plans such as the facilitated inter-institutional IRB review are realized, then there is the potential for a significant enhancement of translational research at each institution and for the partners to accomplish multi-institutional research.
- The CTSI should be highly integrated within the local community as seen from the plans for community engagement and the involvement of community members within the CTSI leadership.

Weaknesses

- Although the UCLA effort is presented as involving faculty from throughout the institution and there are representatives from several schools on the IAC, only the School of Medicine is described in the Resources and Environment section.
- The investigators who are members of the EOC include, with the exception of an informatician, only physicians representing the four sites.

- Given that the CTSA is meant to be multidisciplinary, there is no rationale provided for not including active participation of the leadership of the Schools of Nursing and Dentistry and there are no letters of support from these entities.

Overall

Strengths

- The outstanding strength of the application is the focus on community involvement and benefit, which reflects the leadership of the CTSI and permeates the plan. The strong community engagement component and the potential for collaborations among the four partners and the community that could improve community health are exciting, and the application clearly states that this is a priority.
- The size and the diversity of the local community is perhaps unparalleled within the CTSA consortium and so the opportunities here are great.
- The CTSI has the potential to significantly enhance clinical and translational research within and among the four partners. Although the science is already strong, the additional resources provided by the CTSI will significantly enhance these efforts. It will also allow for the continuation of the former GCRCs at these sites.
- The key elements of the plan include integration of the existing GCRCs and the further development of resources currently based primarily at UCLA with extension to the partners.
- If the vision of devising a common mechanism for protocol management, review, and research privileges across the partners is realized, this will add significant value to the program.
- Institutional commitments, excluding the space commitments, from all four of the partners total \$73 million over five years, which is significant.
- The training program builds upon existing successful programs and significantly enhancing the capabilities.
- The application appears to recognize the issue of partnership considering the size of the UCLA DGSOM relative to the other partners and clearly addresses mechanisms to resolve conflict by designing structures such as the EOC and the ISC to ensure representation.

Weaknesses

- Given the relative size of the research efforts of the four partners, it may be a challenge for the CTSI to operate as a true partnership and not have the UCLA DGSOM overwhelm the other partners. The concept of equity in the allocation is seldom addressed in the application. The differences in the sheer size of the research programs will make this difficult. For example, of the 65 reviewers of the pilot studies, it appears that three reviewers are from Charles Drew and two reviewers are from Cedars-Sinai.
- The non-medical disciplines being represented within the center raise another equity issue.

Critique 2

Integration

Strengths

- There is a strong and credible discussion of how each key component of the CTSI will integrate with the other components.
- The application describes a plan to engage in regional collaborations with other CTSA within the state.
- The application describes a plan to engage in national CTSA consortia and there has already been attendance at national CTSA meetings.

Weaknesses

- None identified.

Overall

Strengths

- The application has responded fully to the issues raised in the prior review.
- The application includes substantial leveraging of the support requested from institutional funds and from contributions.
- The senior members of the CTSI administration are highly qualified and an excellent governance structure is proposed.
- The ongoing biomedical research activity and the number of clinical and translational scientists at the participating institutions are outstanding.
- Strong and integrated academic and community collaborations are included.
- A strong informatics functionality is described.

Weaknesses

- None apparent

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTIONS FOR HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html>.

The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

National Center for Research Resources Special Emphasis Panel NATIONAL CENTER FOR RESEARCH RESOURCES

CTSA II

ZRR1 CR-3 (01)

February 22, 2011 - February 23, 2011

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.