

**SUMMARY STATEMENT**  
( Privileged Communication )

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*Application Number:* 1 U54 HL119893-01

**Principal Investigator**

**PALAZZOLO, MICHAEL J PHD**

**Applicant Organization: UNIVERSITY OF CALIFORNIA LOS ANGELES**

*Review Group:* ZHL1 CSR-O (M1)  
National Heart, Lung, and Blood Institute Special Emphasis Panel  
NIH Centers for Accelerated Innovations

*Meeting Date:* 04/18/2013  
*Council:* MAY 2013  
*Requested Start:* 08/01/2013

*RFA/PA:* HL13-008  
*PCC:* HH N

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*Project Title:* UC BRAID Center for Accelerated Innovation

*SRG Action:* Impact Score: 23

*Next Steps:* Visit [http://grants.nih.gov/grants/next\\_steps.htm](http://grants.nih.gov/grants/next_steps.htm)

**Human Subjects:** 10-No human subjects involved

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

<b>Project Year</b>	<b>Direct Costs Requested</b>	<b>Estimated Total Cost</b>
1	1,294,501	1,972,948
2	2,341,873	3,569,247
3	2,341,873	3,569,247
4	2,341,873	3,569,247
5	2,341,873	3,569,247
6	2,341,873	3,569,247
7	1,292,545	1,969,967
<b>TOTAL</b>	<b>14,296,411</b>	<b>21,789,150</b>

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**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.

## **1U54HL119893-01 PALAZZOLO, MICHAEL**

### **RESUME AND SUMMARY OF DISCUSSION:**

In their discussion, the reviewers of this application generally judged it to be outstanding. The PI, Dr. Michael Palazzolo from the University of California proposed a Center for Accelerated Innovation that will be a consortium between UC Davis, UC Irvine, UCLA, UCSD, and UCSF. A major strength of the proposal is that the research and commercial environments for the Center are outstanding and will build on the existing structure of UC BRAID (Biomedical Research Acceleration, Integration, and Development) and the translational research institute funded by the Clinical and Translational Science Awards (CTSA). Another strength is that the applicants have assembled an impressive list of partners, consultants and advisory board members. The reviewers agreed that the Center will have strong leadership with valuable industry experience, and were impressed that the leadership team is devoting 30% effort to running the Center. They applicants propose a robust approach to technology solicitation, strong metrics analysis, well-developed exit strategies and sustainability, and a good training program. The reviewers felt that running such a large Center would present challenges, but these were mitigated by the strong project management approach. The Center was judged to have strong institutional support and matching funds. A few minor weaknesses were identified. The reviewers had some concerns that regulatory support, intellectual property strategy, and revenue sharing that were not explained well.

### **DESCRIPTION (provided by applicant):**

The University of California Center for Accelerated Innovation proposes to create new mechanisms and to leverage its diverse strengths in diagnostics, therapeutics, and devices to support translation of promising early-stage inventions for patient benefit. The Center is a consortium of the five UC medical campuses: UC Davis, UC Irvine, UC Los Angeles, UC San Diego, and UC San Francisco. Each campus has a thriving research enterprise, nationally ranked medical school, and translational research institute funded by Clinical and Translational Science Awards (CTSA). Together, our five campuses account for nearly 7% of NHLBI's grant funding. The Center taps into the vigor and creativity of California's legendary biomedical and engineering ecosystem and integrates the many successful business, engineering and health sciences programs at our campuses. Our program will partner with well-established biomedical companies, venture capital firms, industry organizations and nonprofits focused on medical innovation. The Center is supported by UC Biomedical Research Acceleration, Integration, and Development (UC BRAID), a joint effort of the five UC biomedical campuses designed to catalyze and accelerate biomedical, clinical, and translational research across the UC system. Together we will: 1) Engage University of California heart, lung and blood disease innovators in entrepreneurship through a comprehensive education, training and mentorship program. 2) Solicit and select technologies with high commercial potential that align with NHLBI's mission and address unmet medical needs or significant scientific opportunity. 3) Incubate our most promising technologies in accordance with industry requirements to facilitate their translation to commercial products that improve patient care and enhance health. 4) Create a high-performing, sustainable infrastructure that will serve as a model to academic research centers. These programs will create an integrated, sustainable infrastructure to accelerate the translation of our NHLBI-funded discoveries to the marketplace in order to promote health and improve patient care.

(End of Abstract)

### **CRITIQUE 1:**

Significance: 2

Investigator(s): 3

Innovation: 3  
Approach: 2  
Environment: 1

**Significance:**

**Strengths**

The proposed UC CAI builds on an existing research network that links the extensive CTSA infrastructure on each of the 5 medical campuses of the UC system (UCLA, UCSD, UCI, UCD, UCSF), called the University of California Biomedical Research, Acceleration, Integration and Development (UC BRAID) consortium. UC BRAID was established two years ago and has been focused on system-wide collaboration to enhance clinical and translational research efforts, specifically policy changes and areas of collaboration. The UC CAI proposal is designed to address the challenge of developing the infrastructure for identifying the highest impact early-stage technologies and translating them to advance health care and benefit patients. Significant non-federal institutional support across the 5 UC campuses totals \$57.7M, including \$8.2M for technology development grants.

Connecting the 5 UC medical campuses through the UC CAI provides a tremendous opportunity to link diverse resources, technology and expertise that should ensure a robust pipeline of new technologies over the course of the 7 year Center grant. The robust and high quality research base funded by NHLBI (nearly 7% of total NHLBI grant funding for 2012 across the 5 campuses, totaling \$195M in NHLBI grant funding in 2012 alone) should provide an ongoing source for a diverse portfolio to sustain the development pipeline for the duration of the award. What is lacking is a UC-wide mechanism for engaging scientists in entrepreneurship and a platform for reaching across the 5 campuses to identify their most promising early technologies and surround them with the right experts and resources to increase the likelihood of commercialization. The UC CAI will fill that gap.

The Center will fund 41 projects over 7 years, and the goal is to double productivity of licensed projects over this time period through support from UC CAI.

The Center proposes to integrate vast and diverse resources and expertise across the 5 medical campuses of the UC system and apply industry-based project management approaches to ensure that the most promising projects get the support they need and progress rapidly to out-licensing or appropriate exit strategies.

**Weaknesses**

A clear statement of need that differentiates the goals of the proposed UC CAI from the existing UC BRAID is lacking, though it is inferred from the brief description of the focus and accomplishments of UC BRAID since its inception in 2010. It appears that UC BRAID has not been in a capacity to provide support for selection and guidance of individual technologies as proposed for UC CAI.

**Investigator(s):**

**Strengths**

The Center Director, Dr. Michael Palazzolo (MD, PhD), is well qualified to lead this effort, with extensive experience in biotechnology pipeline development and management, venture capital, project management, and commercialization in an academic environment. He is Professor of Medicine, Division of Pulmonary and Critical Care at UCLA, and currently manages an international multi-year collaboration between academic labs at U Toronto and UCLA, planned to file its first IND in Jan 2013.

He was a partner at Coastview Capital, an LA-based VC firm that resulted in 7 investments all with successful exits. And previously he was a senior director of biosystems at Amgen and a Director of the Genome Center at Berkeley National Lab, developing tools for high throughput genomics and DNA sequencing. Dr. Ganz (MD, PhD) will serve as Associate Director of the Center. He is Professor of Medicine and Pathology at UCLA and Director of the Will Rogers Pulmonary Research Lab at UCLA. He has successfully transitioned academic discoveries to startups focused on tools and therapies for blood diseases and has served as a consultant for major pharma companies. The Director and Associate Director will report to the Executive Committee, whose members lead UC BRAID and the CTSA's at their respective campuses. Several of the EC members have direct experience with founding startups, including diagnostics companies. Succession plans are in place.

Highly qualified Domain/site leaders have also been identified to cover the platform areas (therapeutics, diagnostics, and devices) and disease areas (cardiovascular, lung & sleep disorders, and blood diseases). Many have been involved in launching startups and/or in licensing new technologies.

The organizational structure is well defined and consists of an Executive Committee, to which the Center Director reports, along with two advisory committees, the External Advisory Board and the Business Review Panel, and one decision-making review panel, the External Selection Committee. The EC is made up of leaders of UC BRAID and in turn links in the infrastructure of the 5 individual CTSA's, already with a strong track record of entrepreneurial innovation and partnerships with the biotech industry in San Diego, Orange County, and San Francisco. The Center will also allow for strong integration of broad expertise and resources within each campus, including those available through the business and engineering schools. Such multi-disciplinary collaborations are already in place within each campus supported by the CTSA's, but would greatly benefit from a focused and well organized effort to link resources and share best practices across the 5 campuses as proposed in the UC CAI.

### **Weaknesses**

Regulatory support has been identified in a general manner, but more detailed description of regulatory support for project teams is lacking. Lack of timely communication with regulatory authorities can be costly. Appropriate preparation and strategizing for pre-IND and pre-IDE meetings is critically important for negotiating pre-clinical development strategies for each technology.

In addition, only 3 project managers have thus far been identified, individuals who are critical to the successful progress of projects entering the Center.

### **Innovation:**

### **Strengths**

A very strong infrastructure consisting of the 5 individual CTSA's is already in place with a strong track record of entrepreneurial innovation and partnerships with the biotech industry in San Diego, Orange County, and San Francisco. The UC CAI will allow for integration of broad expertise and rich resources within each campus, including those available through the business and engineering schools. Such multi-disciplinary collaborations are already in place within each campus supported by the CTSA's, but would greatly benefit from a focused and well organized effort to link resources and share best practices across the 5 campuses as proposed in the UC CAI.

The biggest challenge, and the key gap in the existing individual CTSA's, as well as the recently established UC BRAID consortium, is an integrated approach across all campuses that provides organizational support, technical expertise, input from the business community, IP and licensing advice,

and industry-style project management to increase the "shots on goal" and the number of new technologies translated into real benefit for patients. The UC system has tremendous resources and expertise that could be easily shared and coordinated to realize this goal and the UC CAI will be a catalyst to make this happen.

Strong partnerships with industry (Care Fusion, Quest diagnostics, Pfizer, Med Immune Ventures, Bristol-Myers Squibb, Life Technologies, Edwards Life sciences) have already been established with commitments for in kind support or funding for proof-of-mechanism studies. Institutional partners have also been identified, including the von Liebig Center for Entrepreneurism and Technology Advancement, San Diego Supercomputer Center, Rady School of Management, California Institute for Telecommunications and Information Technology, Business of Science Center, Institute for Technology Advancement, Price Center for Entrepreneurial Studies, UCLA Venture Capital Fund, and Quantitative Biosciences (QB3), who have pledged in kind support, grant funding, business mentoring, and/or entrepreneurial education.

### **Weaknesses**

All the resources and components are in place for strong public-private partnerships that should result in improved translation of new technologies. However, the model and environment are somewhat complicated, which will require strong leadership at many levels and organizational discipline to overcome. The integration of the vast resources and applying them appropriately to a specific project will also require a strong network, knowledge of available expertise, and good execution.

### **Approach:**

### **Strengths**

A tiered technology selection process, modeled after the successful T1 Catalyst Program administered by the UCSF CTSI and the Von Liebig Center for Entrepreneurism and Technology Advancement at UCSD, will be employed. It uses a competitive application process to identify the best translational projects and provide them with customized support that includes expert product development advice and pilot funds. Preliminary proposals submitted as a two-page pre-application online is reviewed by a Review Panel assembled by Domain Leaders, and those having sufficient potential will be invited to submit a full proposal through the Center's portal. A first review is conducted by the EC, Domain leaders and Center leadership, followed by a second review conducted by the ESC.

An External Selection Committee will be comprised of industry experts with extensive experience and technical expertise in all aspects of product development, from discovery to commercialization, and represent a variety of perspectives, including academia, start-ups, regulatory agencies, venture capital, and large pharma companies (preliminary identification of external experts). UC CAI cites the availability of 70+ consultants who are actively engaged in industry full time and who have graciously volunteered to serve as consultants. The proposed schema utilizing industry experts in the ecosystem of the active California bio-economy is innovative as well as unique. Such experts will fill key knowledge gaps to increase the likelihood that proposals entering the center will be scientifically and commercially viable. The Center intends to develop 41 projects over 7 years (3 projects in years 1 and 7, and 7 projects for intervening years). Innovators will be matched with mentors from industry and academia and paired with experienced project managers, and supported by a Skills Development program. A Business Review Panel comprised of faculty with expertise in business transformation will be employed to review options for technologies that will graduate from the CAI, including licensing, start-up formation, or further incubation.

The Project Management strategy is to be a pivotal force in moving advanced UC translational research toward an industrial model focused on developing a high quality product as quickly as possible, and to minimize waste by making timely Go/No Go decisions. The Center Director, Dr Palazzolo, has extensive project management experience in both industrial and academic translational settings, and this is arguably one of the most important considerations for the overall success of the UC CAI. The proposal recognizes that this is one of the biggest challenges in an academic environment that tends to value unstructured creativity over a rigorous project planning approach.

Review criteria for technology selection, including target validation, novelty, and stage of development, unmet need, development feasibility, and IP status are well outlined. Upon entering the Center, a project design team is appointed using matrix management, including experts in the platform and disease areas specific to the project, technology transfer and IP, the innovator, a Skills Program representative, and project management. The project manager will organize meetings, assign deliverables, and author the development plan, which will be completed within two months. Details of a project development plan, whether applied to therapeutic, device or diagnostic, are well outlined and employ standard industry project planning principles including a Gantt chart. The formal project team is assembled once the Project Development Plan is approved by Center leadership. The Domain/Site leader will chair the weekly project team meetings. A monthly meeting involving the Center Director, Associate Director and all Domain leaders will review the status of all ongoing projects utilizing appropriate metrics. A series of risk mitigation strategies are outlined. Short- and intermediate-term goals and metrics are detailed.

### **Weaknesses**

Only 3 project managers covering 41 planned projects have been identified so far. Experienced and technically qualified PMs appropriate for the assigned project could be rate limiting. Overcoming internal silos and connecting innovators with the core functions, expertise and resources internally will be critically dependent on a highly qualified PM. Further, experience in the domain or platform area relevant to the assigned project will be important for the project's success. Also, it is not clear how many projects each PM will be responsible for. On the other hand, outsourced models may not be efficient, especially if the PM is unfamiliar with navigating the local environment. However, given the diverse nature of resources available across the 5 campuses, this is a gap that could be sufficiently addressed over time.

Regulatory support for project teams is not described explicitly, and there is little discussion of IND/IDE planning and submission processes.

The future revenue stream anticipated by IP and licensing appears to channel income back to the individual campuses, with no proportion being diverted to the CAI consortium per se to support its sustainability. A revenue sharing plan that provides a proportion of licensing revenues back to the Center is not described.

### **Environment:**

#### **Strengths**

The 5 medical campuses that comprise the UC CAI (UCLA, UCSD, UCI, UCD, and UCSF) have vast, diverse, and complementary resources that, if leveraged appropriately, could greatly accelerate the achievement of the Center's goals and advance the mission of NHLBI. Further, they operate in a unique bio-economy surrounded by a large biotech presence and entrepreneurial culture. The Center Director and leaders of the existing UC BRAID have already established strong relationships with industry, venture and angel investors, their respective schools of engineering and business, and other

technology partners that positions them well to build on the success they have already achieved in translational research. For this U54 application, they have received letters of support and commitments from a vast array of partners internally and externally that should provide the alliances necessary to transition technologies from discovery to licensing. Further, each CTSA site is resourced with its own TTO that will support each project team under UC CAI. Institutional support is very significant, totaling \$57.7M of in kind and direct support, including a commitment of \$8.2M for matching funds across the 5 UC campuses for Technology Development Grants. Conflict resolution procedures progressing from an informal process, to involvement of the EC, the EAB and NHLBI are well articulated.

### **Weaknesses**

The vastness of the network and resources available present a challenge in terms of support for specific project teams in any one location. This will require strong leadership at multiple levels, organizational discipline, focused project management support that is well connected across the 5 campuses, and outstanding execution. Failure in any of these areas will result in underutilization of available resources and expertise, program delays, and potentially premature termination of projects.

### **Center Administration and Governance:**

#### **Strengths**

This application builds on an existing research network that links the extensive CTSA infrastructure on each of the 5 medical campuses of the UC system (UCLA, UCSD, UCI, UCD, UCSF), called the University of California Biomedical Research, Acceleration, Integration and Development (UC BRAID) consortium. UC BRAID was established two years ago and has been focused on system-wide collaboration to enhance clinical and translational research efforts, specifically policy changes and areas of collaboration, such as clinical data sharing, contracting, and IRB, biobanking, and global informed consent. The UC CAI proposal is designed to address the challenge of developing the infrastructure for identifying the highest impact early-stage technologies and translating them to advance health care and benefit patients.

The organizational structure is well defined and consists of an Executive Committee, to which the Center Director reports, along with two advisory committees, the External Advisory Board and the Business Review Panel, and one decision-making review panel, the External Selection Committee. The EC is made up of leaders of UC BRAID and in turn links in the infrastructure of the 5 individual CTSA's, already with a strong track record of entrepreneurial innovation and partnerships with the biotech industry in San Diego, Orange County, and San Francisco. The Center will also allow for strong integration of broad expertise and resources within each campus, including those available through the business and engineering schools. Such multi-disciplinary collaborations are already in place within each campus supported by the CTSA's, but would greatly benefit from a focused and well organized effort to link resources and share best practices across the 5 campuses as proposed in the UC CAI. The Center Director, Dr. Michael Palazzolo, is well qualified to lead this effort, with extensive experience in biotechnology pipeline development and management, venture capital, project management, and commercialization in an academic environment. Highly qualified Domain/site leaders have also been identified to cover the platform areas (therapeutics, diagnostics, devices) and disease areas (cardiovascular, lung & sleep disorders, and blood diseases).

From an operational perspective, each project accepted into the center will be assigned a project manager and will have a clearly defined project development plan modeled after industrial approaches for decision making. A formal conflict resolution process is well articulated.

An appropriate evaluation and metrics plan is proposed, including short- and intermediate-term goals, overseen by the UC BRAID metrics subcommittee. Potential challenges have been identified with preliminary responses, including missed milestones (supported by EAB input), leadership, and research silos. The latter will benefit in particular from the Governance proposed in the UC CAI, which seeks to integrate vast and diverse resources and expertise and make them available to innovators through a focused project plan.

### **Weaknesses**

A clear statement of need that differentiates the goals of the proposed UC CAI from the existing UC BRAID is lacking, though it is inferred from the brief description of the focus and accomplishments of UC BRAID since its inception in 2010. It appears that UC BRAID has not been in a capacity to provide support for selection and guidance of individual technologies as proposed for UC CAI. The EAB has only 3 committed external experts (though these are highly qualified) and no commitments yet for the External Selection Committee. The governance structure is somewhat complicated and might benefit from simplification in order to streamline processes for review and support. Charters for each of the committees with clear delineation of objectives and roles and responsibilities may help to clarify any overlap.

Silos and disconnects between an innovator or project team and the availability of specific expertise or resources on campus or at sister campuses is a threat to successful progress. The project team meeting structure and connection to the Domain Site leader and ongoing governance reviews should address this, but some operational details and examples are lacking.

### **Technology Solicitation and Selection:**

#### **Strengths**

Connecting the 5 UC medical campuses through the UC CAI provides a tremendous opportunity to link diverse resources, technology and expertise that should ensure a robust pipeline of new technologies over the course of the 7 year Center grant. The robust and high quality research base funded by NHLBI (nearly 7% of total NHLBI grant funding for 2012 across the 5 campuses) will provide an ongoing source for a diverse portfolio to sustain the development pipeline for the duration of the award.

The UC CAI will combine expert customized feedback and advice with funding to help translate promising early stage research into tangible patient benefit. The Center will support concepts in therapeutics, diagnostics, and devices for cardiovascular disease, lung disease and sleep disorders, and blood diseases.

A tiered technology selection process, modeled after the successful T1 Catalyst Program administered by the UCSF CTSI and the Von Liebig Center for Entrepreneurism and Technology Advancement at UCSD, will be employed. It uses a competitive application process to identify the best translational projects and provide them with customized support that includes expert product development advice and pilot funds. A flow chart for engagement and support of innovators is provided and ensures a rigorous review, as well as appropriate support for projects deemed not yet ready to enter the Center, including Consultation Awards supported by the individual CTSA's.

The External Selection Committee will be comprised of industry experts with extensive experience and technical expertise in all aspects of product development, from discovery to commercialization, and represent a variety of perspectives, including academia, start-ups, regulatory agencies, venture capital, and large pharma companies. UC CAI cites the availability of 70+ consultants who are actively engaged in industry full time and who have graciously volunteered to serve as consultants. The

proposed schema utilizing industry experts in the ecosystem of the active California bio-economy is innovative as well as unique. Such experts will fill key knowledge gaps to increase the likelihood that proposals entering the center will be scientifically and commercially viable.

Proposals recommended by the ESC will receive Technology Development Grants of up to \$200,000 over 1-2 years. A sampling of technologies ready to enter the Center includes devices, therapeutics and a diagnostic.

### **Weaknesses**

RFPs occur only once a year, but might benefit from biannual solicitation as already piloted in the T1 Catalyst Program.

The composition of the Expert Selection Committee has not yet been established, and full commitments from the 70+ consultants have not been achieved, though letters of support from many external experts representing diverse areas of expertise are available.

There are no targets for the number of grants funded in each of the separate platform areas, namely therapeutics, devices, and diagnostics. Further, the criteria for prioritizing across platform domains and therapeutic domains has not been established, introducing potential bias in the selection process, depending potentially on the constitutional make-up of the Selection Committee at any particular point in time. Such criteria or guidance should be established before the initial grants are selected, and monitoring of proposals submitted against those funded relative to these domain areas should be conducted, leading to modifications as necessary.

### **Technology Development**

#### **Strengths**

The UC CAI will build on the existing CTSA-funded scientific translation network that integrates the efforts of the 5 UC medical campuses, and leverages institutional support (\$57.7 M) as well as in kind support from the surrounding business community. In addition, each campus brings unique faculty expertise and academic and community resources to the Center in a complementary fashion.

The technology development plan is modeled after the T1 Catalyst Program at UCSF. The Center intends to develop 41 projects over 7 years (3 projects in years 1 and 7, and 7 projects for intervening years). Innovators will be matched with mentors from industry and academia and paired with experienced project managers, and supported by Skills Development program.

Processes for exit strategies have been outlined. The period of incubation will be limited to two years, and if projects are not licensed during this period, the process is subsequently managed by the TTO of the UC in order to maintain capacity to admit new inventions into the Center. A Business Review Panel comprised of faculty with expertise in business transformation will be employed to review options for technologies that will graduate from the CAI, including licensing, start-up formation, or further incubation.

#### **Weaknesses**

Only 3 project managers have been identified so far. Experienced and technically qualified PMs appropriate for the assigned project could be rate limiting. Overcoming internal silos and connecting innovators with the core functions, expertise and resources internally will be critically dependent on a highly qualified PM. Further, experience in the domain or platform area relevant to the assigned project

will be important for the project's success. Also, it is not clear how many projects each PM will be responsible for. On the other hand, outsourced models may not be efficient, especially if the PM is unfamiliar with navigating the local environment.

There is a lack of emphasis on regulatory support at various stages, and no clearly identified regulatory expertise other than general references. Approaches to pre-IND and pre-IDE regulatory interactions are not discussed and critically important for project success.

The IP strategy is not well developed. For example, how will the IP strategy help to prioritize technologies and help shape claims in a patent application? The future revenue stream anticipated by IP and licensing appears to channel income back to the individual campuses, with no proportion being diverted to the CAI consortium per se to support its sustainability.

No rationale is provided for the proposal's stated emphasis on device projects, or if this is consistent with NHLBI focus or with Center expertise. Criteria for funding of projects across the spectrum of the platform areas and the therapeutic areas should be established.

Regulatory support for project teams is not described explicitly, and there is little discussion of IND/IDE planning and submission processes.

## **Project Management:**

### **Strengths**

The Project Management strategy is to be a pivotal force in moving advanced UC translational research toward an industrial model focused on developing a high quality product as quickly as possible, and to minimize waste by making timely Go/No Go decisions. The Center Director, Dr Palazzolo, has extensive project management experience in both industrial and academic translational settings, and this is arguably one of the most important considerations for the overall success of the UC CAI. The proposal recognizes that this is one of the biggest challenges in an academic environment that tends to value unstructured creativity over a rigorous project planning approach.

Upon entering the Center, a project design team is appointed using matrix management, including experts in the platform and disease areas specific to the project, technology transfer and IP, the innovator, a Skills Program representative, and project management. The project manager will organize meetings, assign deliverables, and author the development plan, which will be completed within two months. Details of a project development plan, whether applied to therapeutic, device or diagnostic, are well outlined and employ standard industry project planning principles including a Gant chart. The formal project team is assembled once the Project Development Plan is approved by Center leadership. The Domain/Site leader will chair the weekly project team meetings. A monthly meeting involving the Center Director, Associate Director and all Domain leaders will review the status of all ongoing projects. A series of risk mitigation strategies are outlined.

### **Weaknesses**

As above, lack of sufficient numbers of qualified project managers covering the platform and domain areas for the planned 41 projects could be rate limiting. However, given the diverse nature of resources available across the 5 campuses, this is a gap that should be sufficiently addressed over time.

### **Skills Development:**

## **Strengths**

The Skills Development Program of the UC CAI appropriately has 3 specific aims that includes providing mentoring, programs and activities to expand the pool of innovators, and evaluation and tracking. The Skills Program will seek to orchestrate the development, delivery, and expansion of skills programs across the 5 campuses.

Existing course materials will be leveraged to develop a primer course on the nuts and bolts of technology commercialization that will be offered Center-wide. The Technology Commercialization Primer will consist of at least 5 webinar modules (unspecified), using authentic case examples in each of the domains. These modules will be made available on the Center website to reach the broader innovator community.

An extensive mentoring program for innovators is proposed, supported by external mentors and faculty. Mentors will deliver planned activities and one-on-one mentoring. Three types of mentors will address individual mentor needs: generalist mentors, lead mentors, and specialist mentors.

The Skills Program Leader will report to the Center Director and provide an overall vision and direction for the organization, development and delivery of skills development across the Center. Each campus will have a Skills Program co-leader who will orchestrate skills development initiatives in that campus. Appropriate tracking and metrics have been proposed in order to adjust programs based on feedback and data over time.

## **Weaknesses**

Description of the course offerings and curriculum is somewhat vague, though it appears that various programs are in place across the 5 campuses that will serve as the initial basis for a core curriculum. Similarly, leaders of the skills program have been identified, but faculty for the various course offerings in the curriculum have not.

The applicant acknowledges that a shift in the academic culture and mindset is needed to reach a sustainable phase of productive entrepreneurship, and yet the proposal does not clearly outline a change management approach to specifically address this (though components of a change management plan are part of the overall proposal). Such components include plans for communication, rewards and recognition, involvement and training. Consultation with an organization development expert may be beneficial.

### **Protections for Human Subjects:**

Not Applicable (No Human Subjects)

### **Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

### **Biohazards:**

Not Applicable (No Biohazards)

### **Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Acceptable

**Budget and Period of Support:**

Recommend as Requested

**Overall Impact:**

The proposed UC CAI builds on the existing UC BRAID research network that links the extensive CTSA infrastructure on each of the 5 medical campuses of the UC system (UCLA, UCSD, UCI, UCD, UCSF). The UC CAI proposal will address the challenge of developing the infrastructure for identifying the highest impact early-stage technologies and translating them to benefit patients. Connecting the 5 UC medical campuses and their corresponding CTSA through the UC CAI provides a tremendous opportunity to link diverse resources, technology and expertise that should ensure a robust pipeline of new technologies over the course of the 7 year Center grant. The robust and high quality research base funded by NHLBI (nearly 7% of total NHLBI grant funding for 2012 across the 5 campuses) should provide an ongoing source of new technologies. The Center proposes to apply industry-based project management approaches to ensure that the most promising projects get the support they need and progress rapidly to out-licensing or appropriate exit strategies. The Center Director, Dr. Michael Palazzolo, is well qualified to lead this effort, with extensive experience in biotechnology pipeline development and management, venture capital, project management, and commercialization in an academic environment. Highly qualified Domain/site leaders have also been identified to cover the platform areas (therapeutics, diagnostics, and devices) and disease areas (cardiovascular, lung & sleep disorders, and blood diseases). The 5 medical campuses operate in a unique bio-economy surrounded by a large biotech presence and entrepreneurial culture. The Center Director and leaders of the existing UC BRAID have already established strong relationships with industry, venture and angel investors, their respective schools of engineering and business, and other technology partners that positions them well to build on the success they have already achieved in translational research.

**CRITIQUE 2:**

Significance: 1  
Investigator(s): 1  
Innovation: 3  
Approach: 1  
Environment: 1

**Significance:**

**Strengths**

This proposal integrates and supports activities ongoing at the institutions, enabling additional resources to be placed towards translation of technologies developed with 7% of NHLBI research funding.

The Center makes lean augmentation to existing administration to foster translation of technologies relevant to the NHLBI mission. The administrative structure for institutional collaboration is in place through UC BRAID. Leadership is in place through each institution's CTSA program. The understanding of translation to the clinic is also present through the CTSA programs.

### **Weaknesses**

None

### **Investigator(s):**

### **Strengths**

The executive leadership team has many members with industry experience, including startup, venture capital, and regulatory experience. The leadership derives from all participating institutions. All leaders are also leading CTSA programs at their institutions, and thus are honed in the needs of translational projects.

The Center director based at UCLA will commit 30% time to this effort.

### **Weaknesses**

The site directors anticipate low time commitment; most request salary of 5% or 10% effort.

### **Innovation:**

### **Strengths**

The Center proposes to leverage over 70 mentors with diverse expertise, in ways that advance the translation of technologies. The mentors are assigned defined roles relevant to their expertise. The external advisory board will provide oversight and monitor for the kinds of progress expected on pre-commercial projects.

Resources, personnel and core facilities throughout the participating institutions are well-documented and are integrated into the Center. The facilities are confirmed as available for UC CAI participants.

### **Weaknesses**

The primary additional funding for the Center will come from institutional support. Could some of the commercial partners be expected to bring in more than in-kind support for project advances? Are there reasons (eg IP rights) for not encouraging this?

### **Approach:**

### **Strengths**

Decision-making at the Center level is clearly laid out for timely technology selection, development, and management. Metrics for each step fit the goals, are well-defined, and have clear reporting. Decision-making is conducted with external input, and final decisions are made by someone with business expertise. Conflicts are intended to be minimized, but specific and reasonable plans are in place for resolving conflicts informally and formally.

Skills development is closely tied to technology solicitation and selection. A Consulting Award supports the advance of technologies and the learning of innovators that are not yet ready for full project awards.

Several processes are in place to streamline cross-institution collaboration and leveraging complementary resources.

A Center Portal opens the projects to a wider institutional audience who can follow discoveries, watch video presentations from the innovators. These are models of success.

**Weaknesses**

None

**Environment:**

**Strengths**

The Center builds on a history of collaboration among the institutions established through UC BRAID. The infrastructures between and within institutions are already in place through the UC BRAID and the CTSA programs that are in place in each of the campuses.

As the combined recipients of 7% of the NHLBI research budget, the institutions' comprising this Center have already attracted the interest and support of NHLBI, and has a rich research base of relevance to NHLBI.

Proposal indicates that there is already \$57.7M in institutional support committed over the 7 years of requested funding.

The Center has partnered with the business and engineering schools located at the institutions to access incubator facilities and additional business and product training.

**Weaknesses**

The geographical separation may make travel funds necessary for innovators to conduct technology development at other institutions' core facilities. I don't find these travel funds budgeted.

**Center Administration and Governance:**

**Strengths**

The UC BRAID CAI establishes a lean structure by building on existing administrative structures. UC BRAID already brings the institutions together for collaboration. And CTSA-funded centers at each of the institutions in the proposal provide the directors and administration for each participating institution. Executive leadership and key personnel include several members with industry experience, including startup, venture capital, and regulatory experience.

The institutions have existing structure for benefiting from each other, and this proposal enables them to extend the collaboration for areas of NHLBI interest.

The institutions have created ways to streamline the processes that enable cross-institution collaboration and leveraging know-how and facilities. This includes a common RFP, reciprocity for human subjects review

The Center director will commit 30% time to this effort, and brings ample business experience to the effort.

### **Weaknesses**

For some of the leadership, it is not clear what percent time will be committed to this effort. Normally this would be clear from a requested salary budget but in this proposal many members do not request salary.

### **Technology Solicitation and Selection:**

#### **Strengths**

The technology pipeline results from a rich research base with high relevance to the NHLBI, as recipients of 7% of research funding from this institute.

The skills development programs are an early and broad entry point for soliciting technologies for development.

All final decisions will be made by people with business experience.

The mechanisms for applying for funding, the stages of funding, proposal formats, and criteria for review are clear and detailed. The timeline is define and timely.

There is a mechanism for supporting project proposals and their innovators that are not yet ready for full funding. The Consultation Awards will provide feedback and mentoring for development and potential re-application.

### **Weaknesses**

None

### **Technology Development**

#### **Strengths**

More than 70 mentors have been recruited for the UC CAI, with a variety of expertise. Depending on their expertise, they will have one of several well-defined roles.

A substantial potential allocation per project enables significant progress toward translation and pre-commercial milestones.

The collaboration among institutions provides world-class resources to all projects. The institutions have confirmed their availability and support for the UC-CAI projects.

### **Weaknesses**

None

### **Project Management:**

#### **Strengths**

The proposal details the project development plans, and the experienced project managers already selected for the proposed Center. The proposal conveys confidence that the projects will be managed fairly and with expertise.

An open access portal creates a view on projects, disseminates discoveries, and presentations. This can raise the bar for delivering on milestones through innovators seeing positive examples and sharing in success.

The institutions are streamlining processes to encourage collaboration, including human subjects

### **Weaknesses**

Selecting more Project managers with industry experience will benefit the Center and its focus on commercial metrics and milestones.

### **Skills Development:**

### **Strengths**

The UC BRAID CAI will leverage existing course materials at the five institutions, bring them together to develop a primer course that can be offered Center-wide. The course will have online modules, augmented on individual campuses through in-person interactions. This brings the strongest teaching to the broadest group, in an efficient manner.

The proposal incorporates a large number of mentors, with a wide array of expertise. The proposal lays out different roles for different types of mentors.

Consultation Awards provide directed feedback and support in the pre-funding stage.

Clear metrics are laid out for skill development efforts.

### **Weaknesses**

None

### **Protections for Human Subjects:**

Not Applicable (No Human Subjects)

### **Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

### **Biohazards:**

Not Applicable (No Biohazards)

### **Select Agents:**

Not Applicable (No Select Agents)

### **Resource Sharing Plans:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**Overall Impact:**

The proposed Center builds on existing structures between and within the participating institutions, leverages the strengths, and extends them to benefit the translation of technologies related to the NHLBI mission. The added administrative structure is lean, and budget remains focused on the translational projects. The Center extends opportunities made available through CTSA programs to focus on NHLBI interests.

With a substantial 7% of the NHLBI research funding already going to these institutions, the Center requests added support to translate the resulting technologies in a well-structured environment. Processes and management are clearly laid out, with well defined expectations for projects and metrics for Center success.

**CRITIQUE 3:**

Significance: 3  
Investigator(s): 2  
Innovation: 3  
Approach: 3  
Environment: 4

**Significance:**

**Strengths**

The campuses included in this proposal currently receive 7% of NHLBI funding - so there is a huge significance in supporting the commercialization of this quantity of basic research.

AUTM data shows that while UC as a whole is very good at starting companies they are below their peer institutions in commercializing the research undertaken. The development of this center is being seen as a way to address this problem.

There is a very significant amount of support funding to the proposal that has been committed by the various campuses and by the system - this will ensure institutional commitment to the project and shows that this proposal is intended to be a catalyst for other institutional cultural change. This funding will therefore be very important.

The project is being set-up flexibly so that different campuses can experiment with the commercialization process and they can learn from each others successes and failures.

**Weaknesses**

The proposal is a combination of five campuses and there are a multitude of programs on each campus that are participating - it will be a major management challenge to manage the program and to ensure that resources are being used effectively.

**Investigator(s):**

**Strengths**

The majority of the members of the executive committee and the campus leaders have strong product development and commercialization experience from both industry and academia. The campus leaders also have very strong academic credentials and are recognized in the field as leaders.

Training has been carefully thought out and has a strong business faculty lead that also has significant experience in commercialization of life science technologies.

Many business review panels have been implemented to bring in additional expertise.

Clear succession plan articulated

**Weaknesses**

While there are a number of planned committee meetings for the various committees there may not be enough face-to-face meetings planned for successful communications.

**Innovation:**

**Strengths**

Innovative and creative ideas in allowing program to develop differently on the different campuses and to enable experimentation with different commercialization methodologies.

Within the partnership of campuses award winning projects will be able to gather support and access to a myriad of resources.

The annual forum showcasing technologies that are in the process of being commercialized is creative.

Very strong input from both internal and external experts with industry and product development experience. The award winners will get considerable support in streamlining their research on the commercial viability of the technologies.

**Weaknesses**

Managing such a large number of partner programs could become an issue and also ensuring that access between campuses to each other's resources may be difficult to achieve in practice.

**Approach:**

**Strengths**

The approach is flexible so that lessons learned in one aspect of the program can easily be implemented in other areas.

Very clear advisory board with a lot of industry input will help both select viable projects but also ensure that they have achievable goals within the scope of the commercialization/POC projects

Extensive use of external reviewers and many program supporters from the business communities surrounding each campus.

Clear plans to enable campus programs to interact and support each other.

Clear plans for program management and also to assess go/no go decisions.

New Co program at UCLA looks like a very interesting commercialization model.

### **Weaknesses**

While there is some discussion of smaller seed grants (e.g. the UCSF Catalyst Awards) the majority of the funding is targeted towards \$200K project investments.

There seems little in the plans for how these awards might be cut off and re-distributed should the science in various awards prove to be not commercially viable.

### **Environment:**

#### **Strengths**

The proposal has significant reference to the business communities that are proximate to each of the campuses.

There is considerable use of community business resources in managing the program, selecting projects and supporting the POC experiments.

Clear understanding of the challenges of commercialization.

Strong inclination towards helping faculty PIs learn about entrepreneurship and become more familiar with the requirements of product development vs. basic research.

#### **Weaknesses**

A couple of the campuses have fewer business community resources on which to draw so researchers on these campuses will need to have more support - a plan for this was not articulated.

### **Center Administration and Governance:**

#### **Strengths**

A major strength of this proposal is the thought that has gone into the management and committee structure to support such a complicated multi-campus program.

There has also been considerable thought into how to actually organize the committee functions and schedules to ensure that they work to the benefit of the program.

In addition the quality of the recruits to be committee members and to serve in other advisory functions to the project is extremely high.

Strong back-office processes will be transferred from other campus programs to support the management of this program.

Full-time program manager at UCLA to maintain control of all projects and to ensure that there is appropriate monitoring of projects.

**Weaknesses**

There are a lot of program managers and some of these will not be full-time on each campus - so that it will be a challenge to ensure that they focus on this project - with the exception of a full-time program manager at UCLA noted above.

**Technology Solicitation and Selection:**

**Strengths**

This part of the proposal is very strong - good outreach on each of the campuses to solicit ideas and proposals

Support of proposers that are not funded to help them re-propose if there is a viable idea that was not well articulated.

Very high level of external involvement in the selection of projects for funding.

**Weaknesses**

None

**Technology Development**

**Strengths**

Domain experts both academic for internal support and external for industry support have been identified to help the development of the projects.

Good ip management on the campuses and clear inclusion of TTOs.

Very high level of institutional commitment to the projects and to fund projects.

UCSD has instituted express licenses and these are being considered by other campuses.

**Weaknesses**

None

**Project Management:**

**Strengths**

Business review panels have been established to support projects.

Clearly assigned project managers with responsibility to manage and report on the progress of each project and to ensure that researchers get the resources they need.

**Weaknesses**

None

**Skills Development:**

**Strengths**

Thoughtful proposal on skills development including the use of many existing resources.  
Strong lead by UCSD in this area.

**Weaknesses**

None

**Protections for Human Subjects:**

Not Applicable (No Human Subjects)

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Select Agents:**

Not Applicable (No Select Agents)

**Resource Sharing Plans:**

Acceptable

Comments (Required if Unacceptable)

There are a lot of resources within the 5 campuses that will be used and there is adequate management oversight to ensure that researchers get access.

**Budget and Period of Support:**

Recommend as Requested

Recommended budget modifications or possible overlap identified (if applicable)

Reallocation of some of the major grant awards to smaller awards to develop a pipeline of projects and to make no go decisions easier to manage.

**Overall Impact:**

This is a very well thought out proposal and well articulated as to how the program will be established and managed. There are several creative elements to the proposal including having additional public events to show case new technologies. One of the most impressive aspects of this proposal is the inclusion of many faculty on the program that have significant industry experience who will help guide the program. There is also a very significant amount of external business input and support that has been garnered to help the program meet its objectives.

(End of Reviewers' Comment)

**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:**

**COMMITTEE BUDGET RECOMMENDATIONS:** The budget was recommended as requested.

**SRO NOTE:** Final budgets will need to be negotiated with NHLBI Program and Grants Management staff if an award is contemplated.

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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. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer\\_review\\_process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).

## MEETING ROSTER

**National Heart, Lung, and Blood Institute Special Emphasis Panel  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
NIH Centers for Accelerated Innovations  
ZHL1 CSR-O (M1)  
April 18, 2013 - April 19, 2013**

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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.