OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier
EB014315

b. Agency Routing Number

2. DATE SUBMITTED

Application Identifier
P0504173

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION **Organizational DUNS*:** 0948783370000

Legal Name*: The Regents of the University of California, San Francisco
Department: Research Management Services
Division: Office of Sponsored Research
Street1*: 3333 California Street
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County:
State*: CA: California
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Country*: USA: UNITED STATES
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Person to be contacted on matters involving this application
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6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1946036493A6

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

❍ New ❍ Resubmission
❍ Renewal ❍ Continuation ● Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ● E. Other *(specify)* : Diversity Supplement

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Biocompatibility of Implantable Renal Replacement Devices

12. PROPOSED PROJECT
Start Date* Ending Date*
11/01/2014 04/30/2016

13. CONGRESSIONAL DISTRICTS OF APPLICANT
CA-012

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Shuvo Middle Name: Last Name*: Roy Suffix: Ph.D
Position/Title: Professor
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Division: School of Medicine
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15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$185,776.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$185,776.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

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Signature of Authorized Representative* **Date Signed***

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)	
2. Specific Aims	
3. Research Strategy*	Research_Experience_Plan_final.pdf
4. Progress Report Publication List	

Human Subjects Sections

5. Protection of Human Subjects	
6. Inclusion of Women and Minorities	
7. Inclusion of Children	

Other Research Plan Sections

8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	
11. Consortium/Contractual Arrangements	
12. Letters of Support	Letters_of_support.pdf
13. Resource Sharing Plan(s)	

Appendix (if applicable)

14. Appendix	

"Surgical Considerations for Implantable Renal Replacement Devices"

A. CANDIDATE

Dr. Willieford Moses graduated from Duke University in 2006 with a Bachelor of Science in Psychology and a minor in Chemistry. He attended medical school at the University of California, San Francisco (UCSF), where he graduated in May of 2011 and was accepted into the UCSF general surgery residency program, a seven-year training program that includes two years of dedicated research during years four and five. Willie completed his third postgraduate year this past June 2014, and began the first of his two years devoted exclusively to research in July. His work is currently funded through internal funding held by the Division of Pediatric Surgery at UCSF until dedicated funding for his work on the current project can be obtained.

Willie has quite an impressive track record in research from his time in medical school. While a medical student, Willie successfully applied for the UCSF School of Medicine Dean's Research Fellowship (awarded in 2007 and 2008), which enabled him to conduct multiple translational research projects under Electron Kebebew, MD, in the Endocrine Division of the Department of Surgery. Willie's primary project focused on evaluating the diagnostic and prognostic utility of BRAF mutation genotyping through a prospective trial of patients undergoing surgery for papillary thyroid cancer. His findings resulted in 7 publications, including 3 as first author, in multiple journals including *Thyroid* and *Cancer*. During medical school he also conducted research at Makerere University in Uganda under Jane Fualal, MD, to identify and characterize barriers to care in thyroid disease in the country. His findings were published in the *World Journal of Endocrine Surgery*.

Willie's early research experiences at UCSF and Makerere University awakened a desire to bridge bench-work with the clinical setting through translational research. Since beginning general surgery residency, his research interests have continued to evolve towards the area of medical device innovation, a field in which surgeons are particularly suited to contribute to advancements in care through their unique role as "engineers" of solutions in the operating room and the accompanying stimulus to think of better methods and devices to improve patient outcomes. An aspiring surgical innovator, Willie has chosen to spend his two research years during residency in my lab laying the groundwork for the clinical implementation of the implantable bioartificial kidney. As the only full-time hands-on surgeon on the team, Willie will fill the critical role of investigating approaches around the surgical feasibility of device implantation. Through the experience of working through the translational challenges of demonstrating safety and performance of the artificial kidney in an *in vivo* model, Willie will learn first-hand the process of bringing new technology into the realm of clinical reality.

From my interactions with Willie over the past several months as he has designed and planned his project, I have found him to be extremely bright, hardworking, resourceful, and motivated. Based on these qualities, the high productivity of his prior research experiences, and his rigorous clinical training to date, all signs point to Willie's continued success as he progresses towards his goal of becoming an academic surgeon-innovator. I am confident that this proposed research experience will add foundational bioengineering knowledge as well as the technical and professional skills necessary for him to mature into a successful independent clinical investigator engaged in medical device innovation for the benefit of his patients.

B. SUMMARY OF SPECIFIC AIMS OF PARENT GRANT

End-stage renal disease (ESRD) affects over 500,000 Americans and costs Medicare almost $35 Billion annually (1). Unfortunately, renal transplant as a treatment option is severely limited by shortage of donor organs, while dialysis is expensive, inconvenient, and confers significant morbidity and mortality (1, 2). We have embarked on a long-term project to develop an implantable bioartificial kidney for the treatment for ESRD. In its envisioned implementation, the implantable renal replacement device will consist of a parallel-plate hemofilter constructed from silicon nanopore membranes (SNM) combined with a bioreactor of human renal tubule cells to mimic nephronal function. Initial pilot studies supported by a NIH/NIBIB-sponsored Quantum Grant (1R01EB008049) along with previous awards allowed our team to establish concept feasibility and identify critical implementation roadblocks to project success (3-8). Among them, a key challenge will be the long-term blood compatibility of the hemofilter with respect to clot formation (thrombosis) and plasma protein adsorption (membrane fouling).

The factors limiting 3-month hemofilter performance need better definition in preparation for future preclinical studies. Consequently, the work in the parent grant project is focused on improving our understanding of blood-device interactions spanning from molecular to histologic and anatomic length scales, and examining whether a hierarchical strategy can be applied to optimize hemofilter biocompatibility. *We hypothesize that device failure modes in the implanted hemofilter segregate by length scale, as high-volume flow in a duct is phenomenologically distinct from macromolecular hindrance at the entry region of a pore.* In the parent grant, we have two specific aims to examine this hypothesis using our prototype SNM hemofilters:

1) Evaluate impact of membrane surface physicochemical properties on mass transfer characteristics of the hemofilter.
2) Determine role of fluid flow anomalies such as flow separation, eddy zones, and shear stress in hemofilter thrombosis.

C. RESEARCH PLAN TO BE CARRIED OUT BY DIVERSITY CANDIDATE

The long-term goal of the overall research effort is to develop an implantable bioartificial device to provide renal replacement therapy for the treatment of end-stage renal disease (ESRD) patients. The initial *in vivo* experiments described in the parent grant focus on understanding how blood-membrane interactions affect the biocompatibility of the hemofilter device (HemoCartridge) with an emphasis on mass transport and thrombosis. **In contrast, Willie's project will evaluate hemofilter biocompatibility as it pertains to surgical implantation factors.** Specifically, Willie will be working to optimize the interface of native tissue with the HemoCartridge in a large animal model (pig) through the following specific aims:

1) Determine the optimal vascular interface between the HemoCartridge inlet and outlet conduits and native blood supply.
2) Investigate the material characteristics and biocompatibility of the HemoCartridge housing with respect to surgical placement and device stability *in vivo*.

AIM 1: Determine the optimal vascular interface between the HemoCartridge inlet and outlet conduits and native blood supply.

Rationale: Ultrafiltration will require an adequate supply of blood to the HemoCartridge in order to effectively provide renal replacement therapy. This supply of blood will be contingent upon a delivery system that connects the device to the native vasculature and remains patent long-term. We will investigate the following questions surrounding securing/delivering an adequate blood supply to the HemoCartridge: (1) What is the ideal native artery, vein and anastomotic technique to provide adequate blood to the device? (2) What are the optimal characteristics of the vascular graft conduit (e.g. material, length, and diameter)? *We hypothesize that an end-to-side anastomosis of 6-mm PTFE grafts to the external iliac artery and vein of a Yorkshire pig will maintain adequate pressure and flow through the HemoCartridge while allowing for distal limb perfusion in the pig.*

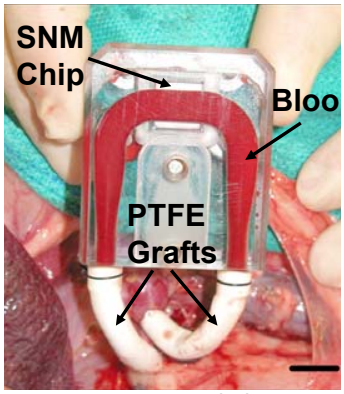

Figure 1: Early proof of concept model in mini-pig. PTFE graft attached to device with silk tie and anastomosed to blood vessels with prolene suture

Methods: We will assess the impact of the various surgical factors shown in **Table 1** below on blood delivery and device perfusion using computational analysis followed by *in vivo* experimentation in a Yorkshire pig model. To begin, mock designs of arterio-venous connections of varying configurations will be created with SolidWorks computer aided design (CAD) software. Design variations will include grafts of varying diameter and length, end-to-side vs. end-to-end anastomosic connections, and different angles of intersection between the anastomosed vascular grafts and vessels. The various designs will be analyzed with computational fluid dynamics (CFD) simulation tools, and the most promising configurations will be experimentally evaluated *in vivo* in the porcine model. Initial experiments will use synthetic polytetrafluoroethylene (PTFE) grafts due to their known low thrombogenic and infection properties, with synthetic polyester grafts (Dacron) evaluated as an alternative if needed. Per the parent grant protocol, the device will be implanted and grafts will be anastomosed in end-to-side fashion to the external iliac artery and vein of Yorkshire pigs. According to anatomic studies (9), these vessels should be of sufficient size to accommodate a 6mm graft without compromising distal limb ischemia (steal syndrome). Alternative vessels and anastomotic connections will be evaluated as needed. Grafts will be monitored for the duration of the experiments to establish primary patency rates. Flow characteristics through the grafts will be continuously measured via an internal Doppler probe placed at the time of implantation. Vascular anastomoses as well as distal extremity perfusion will be serially monitored with transcutaneous Doppler. At the conclusion of the study (30 days per parent grant based on prior proof of concept experiments), animals will be euthanized and the arterial and venous anastomoses will be fixed in formalin via sacrifice perfusion and subsequently explanted. Histologic (haematoxylin-eosin, elastic-van Gieson, and masson's trichrome), morphometric and immunohistochemical (CD31, CD45, CD68) analyses will be performed to evaluate for evidence of inflammation and early signs of neointimal hyperplasia (10-12).

Table 1. Vascular interface variables to be evaluated in Aim 1.

	Hypothesis	Alternative(s)	Criteria for Success
Vessel selection	External iliac artery + vein	Renal hilum, aorta and IVC	- Adequate perfusion of HemoCartridge - Surgically feasible - Low complication rate
Graft material	PTFE	Dacron	- Non-thrombogenic - Compatibility with connector device
Graft size	6mm diameter	5mm to 8mm grafts	- Adequate perfusion of HemoCartridge - Distal tissue perfusion maintained
Vessel-to-graft connection	- End-to-side anastomosis - [30-degree angle of intersection]	- End-to-end anastomosis - [45-degree angle of intersection]	- Prevention of neointimal hyperplasia - Adequate perfusion of HemoCartridge - Distal tissue perfusion maintained - Prevention of turbulent flow

Expected outcomes and alternative strategies: These tests will allow us to identify the optimal blood vessels, device-graft-vascular interfaces, and graft specifications to be incorporated into the clinical-grade HemoCartridge. Evidence of steal syndrome, distal ischemia, or inadequate flow through the device will necessitate modification to aspects of the graft design and/or surgical protocol, which could include altering the blood vessels used (more central, e.g. aorta, inferior vena cava, etc.), graft material type (PTFE vs. Dacron), length and diameter of graft, type of anastomoses (end-to-end vs. end-to-side), and/or variation in the connection of the graft to the device itself. **Criteria for Success:** Adequate perfusion of the cartridge sufficient to maintain ultrafiltration (blood flow rate of at least 100ml per minute, systolic pressure of at least 60 mmHg), minimal evidence of neointimal hyperplasia, and maintenance of graft patency and distal tissue perfusion for at least 30 days.

AIM 2: Investigate the material characteristics and biocompatibility of the HemoCartridge housing with respect to surgical placement and device stability *in vivo*.

Rationale: Implantation of a biomedical device can result in a foreign body response (protein deposition, enzymatic degradation, inflammation, encapsulation, biofouling, leeching, etc.) from interactions of the device material and local tissue (13, 14). This response can have deleterious effects to the host both locally and systemically (systemic toxicity, infection, pain, etc.) and can lead to early device failure. The foreign body response, however, can be mitigated based upon the design of the interface of device material and tissue (15, 16). To optimize long-term viability of the implanted HemoCartridge and minimize adverse reactions, the physical properties of the HemoCartridge housing material as well as its surface chemistry will need to be carefully selected. We aim to investigate these modifiable factors of the external shell of our device and their impact on the biocompatibility *in vivo* in order to determine the optimal housing of the clinical-scale device. *We hypothesize that titanium will minimize adverse local tissue inflammation that could otherwise lead to infection, early device failure, and adverse patient effects.*

Methods: We will investigate the impact of various alterations in the external housing of our device through both finite element modeling and *in vivo* comparisons of different external shell models (**Table 2**). As in Aim 1, various configurations of the external shell will be designed in SolidWorks and evaluated by finite element analysis, and the most promising will be tested in the pig model. Our initial tests will compare the loco-regional effect and foreign body response profile of a titanium shell versus stainless steel as a control. Based on results, we will consider the need for surface coating modifications. The encased HemoCartridge will be implanted into the iliac fossa of a Yorkshire pig per the parent grant protocol and anastomosed to the iliac artery and vein. To assess for biofouling and inflammation, at the conclusion of the study (30 days), the device will be explanted en bloc with surrounding tissue via sacrifice perfusion fixation. The loco-regional effect of the device on the native tissue will be assessed via histologic analysis of the inflammatory peel enclosing the device at time of sacrifice for evidence of fibrosis and/or ongoing active inflammation. H&E staining and morphometric analyses will be done to evaluate for presence of inflammatory cells, debris and/or microbes. The device surface will be analyzed for protein absorbency by Bradford protein method (17) and Coomassie Blue staining. Anastomotic leak rate will be monitored during *in vivo* testing, serving as a potential proxy for tension and stress at the anastomotic suture line due to untoward mobility and movement of the device.

Table 2. HemoCartridge housing factors to be evaluated in Aim 2.

	Hypothesis	Alternative(s)	Criteria for Success
Housing material	Titanium	- Stainless steel - Coating	- Absence of fibrosis and inflammation on histology - Absence of protein adhesion on surface
Fixation mechanism	None required	Similar to portacath	- Adequate flow and filtration maintained - Absence of anastomotic leak or failure - Surgically feasible

Expected outcomes and alternative strategies: We expect that titanium will serve as a bio-inert material to house the HemoCartridge, as it is an accepted implantable material for other devices (e.g., mechanical assist devices, pacemakers, etc.). Evaluation of the device after implantation will allow for identification of the material and fixation mechanism that minimizes impact on the efficiency of the cartridge as well as on the local tissue. Evidence of inflammatory debris, fibrosis, or inadequate flow through the device will necessitate modification to the device form factor and/or surgical protocol, which could include altering the shape, size, coating, orientation, material, or method of fixation into the fascia. **Criteria for Success:** To ensure our device has a biocompatibility profile sufficient for long-term implantation, success will be based upon minimizing on-going inflammation and infection of the device consistent with published data from other devices of the same material in clinical practice currently (e.g., pacemakers, ventricular assist devices, etc.)

How this research enhances the candidate's research potential, knowledge, and skills: As a resident physician training to become an academic surgeon with an independent research interest in medical device innovation and translational work, this project is an apt vehicle for developing Willie's technical and professional skills as a surgeon and researcher, and the experience will greatly enhance his potential to succeed in such endeavors as an independent investigator. As the research plan describes, many unanswered questions (e.g., vascular and hemocompatibility) surround the surgical implantation of the bioartificial kidney that are distinct from other implantable devices on the market currently. As such, the project necessitates the development of innovative surgical approaches with respect to the design and technical aspects for implantation—approaches which Willie, as the only full-time, hands-on surgeon on the team, will be responsible for pioneering with guidance from his surgical mentors. Through the process of answering these questions and subsequently working with the engineering team in my lab to iterate the device based on the knowledge gained, Willie will develop strong problem-solving abilities as well as interdisciplinary collaboration skills through learning to bridge the engineering and clinical realms. This experience, along with the fundamental skills of conducting *in vivo* experiments in animal models, trouble-shooting protocols, and analyzing the findings in the context of direct clinical utility, will give him the background and tools to successfully engage in surgical innovation and device development for the rest of his career.

Table 3. Research Timeline: July 2014 – June 2016

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Graft-device interface R&D	■							
Graft-device interface modeling		■						
Preliminary *ex vivo* biocompatibility experiments		■						
External design research and modeling		■	■					
Phase I *in vivo* experiments			■	■		■	■	
Histologic evals for intimal hyperplasia				■			■	
Graft-device interface redesign				■	■			
External design modification					■	■		

D. RELATIONSHIP TO PARENT GRANT

The longevity and ultimately, clinical utility, of the bioartificial kidney will depend on the design of various internal and external aspects of the device. The parent grant has two specific aims focused on the internal functioning of the hemofilter device: (1) Evaluate the impact of membrane surface physicochemical properties on mass transfer characteristics of the hemofilter, and (2) determine the role of fluid flow anomalies such as flow separation, eddy zones, and shear stress in hemofilter thrombosis. Accordingly, the experiments described in the parent grant seek to assess the overall impact of blood flow on the hemofilter with respect to retained efficiency and functionality as it becomes exposed to blood products, specifically examining the membranes in the hemofilter as well as the blood flow path within the hemofilter. Willie's project will focus on

the external factors (housing material and type of anastomotic connection) that also affect biocompatibility, particularly the surgical factors surrounding device implantation and their effect on device performance and clinical feasibility/safety. Essentially Willie's work will enhance the studies in the parent grant by enabling successful surgery, which is necessary and within the scope of the parent grant.

E. CAREER DEVELOPMENT PLAN

As a surgeon-in-training only a few years removed from medical school, the experience of being embedded in a bioengineering lab will be novel for Willie, providing him with many new learning opportunities. Medical device research and development relies upon in-depth interdisciplinary collaboration between engineers, scientists, and clinicians, and in order for surgeons to engage effectively in this pursuit, a baseline working knowledge of the key technical, business, and regulatory principles at play is critical. In recognition of these needs, UCSF recently created the Innovation Pathway, which provides surgical residents who are interested in pursuing device innovation as their career research focus with specialized training and preparation to complement their hands-on research experiences (see http://residentresearch.surgery.ucsf.edu/research-pathways/research-pathways/surgical-innovation.aspx). Willie will also receive training in SolidWorks and ANSYS simulation software for shape optimization and CFD modeling and will work closely with Dr. Roy and other engineers within the lab as he incorporates this training into his project. In addition to the bioengineering and entrepreneurship knowledge Willie will gain, he will also be trained in the foundational research and professional skills (e.g. scientific writing and grantsmanship, biostatistics, clinical research design) necessary for succeeding as an academic clinical investigator. He has already started taking courses this summer at the UCSF Clinical & Translational Science Institute (CTSI) and as demonstrated below, he will continue taking courses throughout the two years to supplement and enhance his research experience.

In order to build Willie's record of research productivity and professional network, Willie will target abstract submission and presentation at the annual American Society of Artificial Internal Organs (ASAIO) conference and at the annual national surgical conferences for the American Pediatric Surgical Association (APSA) and the American Society of Transplant Surgeons. He will also prepare and submit manuscripts describing his results to at least one peer-reviewed engineering journal and at least one peer-reviewed surgical journal. Finally, Willie will present his progress annually at the Department of Surgery Grand Rounds as well as weekly at the Roy lab meeting. These experiences will further develop his communication and presentation skills.

Table 4. Timeline of Supplementary Coursework and Career Development Milestones

	Fall 2014	Spring 2015	Fall 2015	Spring 2016
General Research Courses	- EPI 150.03: Designing Clinical Research - EPI 227: Building a Career in Clinical Research	- Department of Surgery Scientific Writing Course	- BIOSTAT 193: Introduction to Statistical Analysis	- EPI 212: Publishing & Presenting Clinical Research - Grant Writing Workshop on Mentored Career Development Awards
Bioengineering & Entrepreneurship Courses	- Intro to ANSYS Mechanical - Intro to ANSYS CFX	- BIOE 270: Translational Challenges: Diagnostics, Devices & Therapeutics	- Lean Launchpad for Life Sciences & Healthcare	
Milestones		- Present at major engineering conference	- Manuscript preparation & submission	- Present at major surgical conference

F. MENTORING PLAN

1. Qualifications of Mentor: Willie's primary mentor, Shuvo Roy, PhD, is Professor of Bioengineering and Therapeutic Sciences at UCSF and Director of The Kidney Project, a national research project to develop an implantable total renal replacement therapy. A leader in the field of biomedical microelectromechanical systems (bioMEMS) research, Dr. Roy has many successful ongoing collaborations with surgeons and physicians in the area of medical devices and is an experienced and sought-after mentor for clinicians and bioengineers alike, having mentored 14 predoctoral trainees and 6 postdoctoral trainees. Dr. Roy's previous and current clinical mentees include William Fissell, MD, Associate Professor at Vanderbilt University and Medical Center; Paul Brakeman, MD, PhD, Associate Professor at UCSF; and Steven Kim, MD, nephrology fellow at UCSF. Postdoctoral bioengineering mentees include Alvaro Mata, PhD, Associate Director of Strategic Partnership, Queen Mary University of London; Lisa Ferrara, PhD, CEO, OrthoKinetic Technologies; and Eun Jung Kim, PhD, postdoctoral scholar at UCSF.

2. ***Mentoring Plan.*** Willie will be mentored by a multidisciplinary mentorship committee led and coordinated by Dr. Roy. As PI of the parent grant and primary research mentor, Dr. Roy will provide the technical expertise and engineering guidance necessary for Willie to achieve the aims of his proposed sub-project, as well as oversight of the overall progress of Willie's research including his progress towards productivity milestones. Dr. Roy will meet with Willie weekly and more frequently as needed. Recognizing that Willie is a clinical trainee, Willie will have two additional co-mentors from the Department of Surgery to provide career and research guidance from a surgical perspective. Specifically, **Hanmin Lee, MD,** Division Chief of Pediatric Surgery, Surgeon-in-Chief of the UCSF-Benioff Children's Hospitals, and Director of the Department of Surgery's Innovation Pathway, will serve as Willie's career mentor, meeting with Willie monthly to ensure progress towards his career goal of becoming a fellowship-trained academic pediatric surgeon and to advise him as to successfully participating in and leading device innovation efforts as a surgeon. **John Roberts, MD,** Division Chief of Transplantation Surgery and Chief of UCSF Medical Center's Transplantation Service, will serve as Willie's primary surgical mentor. Dr. Roberts has an outstanding track record as a mentor for surgical trainees and will meet with Willie monthly and more frequently as needed to discuss technical strategies for the device implantation surgeries and to troubleshoot and explore new approaches as needed. The mentorship committee will convene quarterly to review the progress of Willie's project towards its stated goals as well as to monitor the progress of Willie's professional development and identify opportunities to promote his career growth and independence. One such strategy will be for Willie to take on mentorship of a beginning bioengineering graduate student in the lab in order to help him develop his own teaching and mentoring skills. As all members of the mentorship committee have previously worked with Willie in various clinical capacities during his three years as a general surgery resident, they are each able to contextualize this experience within his overall career plan and trajectory.

Additionally, to augment the clinical expertise available to Willie as he works to enable successful *in vivo* implantation of the hemofilter, he will be advised by three consulting surgeons with expertise in various areas relevant to the project. **Georg Wieselthaler, MD,** Director and Surgical Chief of Cardiac Transplantation and Mechanical Circulatory Support at UCSF, will advise on the method of anastomotic connection and graft material selection from his experience in the development and implantation of some of the world's first ventricular assist devices (VADs). **Christopher Owens, MD,** and **Shant Vartanian, MD,** from the Division of Vascular and Endovascular Surgery at UCSF will provide oversight with respect to the surgical procedures based upon their research experience with vascular grafts in swine models.

3. ***Transition Plan.*** At the end of his two-year research experience on the artificial kidney project, Willie will resume the clinical portion of his residency training for two more years, followed by a two-year fellowship for specialized clinical training in pediatric surgery. At this point, he will be positioned to begin a faculty position and seek mentored K-award funding to support his research as a new investigator. Willie's experience as an NIH-supported diversity fellow on The Kidney Project will increase his competitiveness for both a faculty and fellowship position, as well as K-award funding. All members of the mentorship committee are committed to Willie's long-term success, and will continue mentoring and advising Willie beyond the term of the present project to ensure that he transitions successfully to independence as an academic physician-investigator.

G. PROMOTING DIVERSITY

African Americans are significantly underrepresented in academic surgery, comprising a mere 2.9% of academic surgeons in the United States, compared with 74.1% for whites, 10.8% for Asian Americans and 3.6% for Latino Americans (18). This supplement proposes to support the research career development of an extremely promising young African American surgeon by providing a high profile, national-scale project as his training ground that is further augmented by tailored comprehensive mentoring and career development activities. Willie's success on this project and in the future will raise the profile of African Americans in medicine and science both locally and on the national level. The Kidney Project is an institutional priority project at UCSF and receives frequent media attention. Willie's involvement and contributions to the project will be highlighted at every opportunity. He will have several opportunities to present his work at national conferences as well as publish in high-impact journals.

The project also offers the opportunity for Willie to conduct research in an area that directly impacts the African American community. For a variety of reasons, ESRD disproportionately affects blacks as compared to whites in the United States by a ratio of 4:1 (19). Access to appropriate care and treatment is limited, particularly with respect to transplant availability. By helping to define an alternative means by which renal replacement therapy can be effectively administered in a sustainable fashion, Willie will be directly contributing to reducing the burden of a serious public health problem in the African American community.

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August 26th, 2014

Shuvo Roy, PhD
Professor of Bioengineering
UCSF School of Pharmacy
1700 4th Street
San Francisco, CA 94158

Dear Dr. Roy and Collaborators:

Thank you for inviting me to serve as both a collaborator on the research and development of the artificial kidney as well as for the opportunity to partake in the career development of Dr. Willieford Moses as one of his co-mentors during his time in your Biodesign lab.

As you know, I have worked with Willieford in a clinical capacity over the past 3 years during his general surgery residency training on our Pediatric Surgery Service here at the University of California, San Francisco (UCSF). Over the course of that time I have been able to oversee his development clinically as a surgeon. With expressed interest in pediatric surgery and device development, he decided to join the Innovations Pathway through our Pediatric Surgery Division which is a program that I have overseen devoted to the career development of surgical residents interested in medical technology innovation and entrepreneurship.

As part of my role on this current project, I will plan to work directly with Willieford on his research investigating the surgical considerations for implantation of the artificial kidney. I will plan to meet with him regularly to review his project, offer surgical expertise and more generally to co-mentor him as he progresses through your Biodesign lab.

I look forward to working with you on this project and providing surgical mentorship to Willieford Moses as he works with your team.

Sincerely,

Hanmin Lee, M.D.
Surgeon in Chief, UCSF Benioff Children's Hospital
Professor & Chief, Division of Pediatric Surgery, UCSF

University of California
San Francisco

UCSF

Liver Transplant Program

505 Parnassus Avenue
Room M-896, Box 0780
San Francisco, CA 94143-0780
tel: 415/353-1888
fax: 415/353-8709

September 4th, 2014

Dr. Shuvo Roy, PhD
Professor of Bioengineering, UCSF
1700 4th Street
San Francisco, CA 94158

Dear Dr. Roy:

I am writing to confirm my interest in collaborating with you and co-mentoring Willie Moses while he investigates the surgical considerations for implanting the HemoCartridge on your artificial kidney project.

I am a board-certified general surgeon with fellowship training in transplant surgery. I currently serve as Professor and Chief of the Division of Transplant Surgery at the University of California, San Francisco. I have previously served as the president of the national Organ Procurement and Transplantation Network and United Network for Organ Sharing (UNOS).

As a collaborator on your project, I plan to offer expertise and oversight to Willieford Moses as he works in your Biodesign lab to investigate the necessary external components (i.e., exo-skeleton and vascular conduits) of the device to make it appropriate for implantation. As Willie is also one of the surgical residents in training here at UCSF, I will also plan to make myself available to him for career advice and mentorship as he develops into an academic surgeon researcher.

Sincerely,

John P. Roberts, M.D.
Professor and Chief, Division of Transplant Surgery
Chief, UCSF Medical Center Transplant Service
Endowed Chair in Abdominal Transplantation

University of California
San Francisco

UCSF

Department of Surgery
Division of Cardiothoracic Surgery

Georg M. Wieselthaler, M.D.
Professor of Cinical Surgery
Director and Surgical Chief
of Cardiac Transplantation and
Mechanical Circulatory Support
Division of Cardiothoracic Surgery

500 Parnassus Avenue, MUW-405
San Francisco, CA 94143-0118
Academic Tel: 415/353-8890
Clinical Tel: 415/353-4145
Fax: 415/353-4716
Georg.Wieselthaler@ucsfmedctr.org
www.cardiacsurgery.ucsf.edu

September 2, 2014

Dr. Shuvo Roy, PhD
Professor of Bioengineering
School of Pharmacy
University of California, San Francisco
1700 4th Street
San Francisco, CA 94158

Dear Dr. Roy:

I write this letter to confirm my interest in collaborating with you on your research developing an artificial kidney.

As you know, I am a heart transplant surgeon at UCSF with expertise in mechanical circulatory assist devices. In 2006, I was the first to implant the HeartWare HVAD. Over the last two decades, I have directly participated in the research and development of numerous implantable devices, serving as a principal investigator on multiple projects. As such, I am particularly knowledgeable in the field of artificial device implantation.

I plan to work directly with Willieford Moses, providing input as he develops strategies for implanting the hemofilter into pigs. I will advise him on housing design considerations based on my prior experience. . I will meet with him regularly to review his progress and offer my expertise where applicable.

I look forward to collaborating with you through this project.

Sincerely,

Dr. Georg Wieselthaler, M.D.
Professor of Surgery
Director & Surgical Chief
Cardiac Transplantation and Mechanical Surgical Support
Division of Adult Cardiothoracic Surgery
500 Parnassus Avenue
San Francisco, CA 94143-0118

UCSF
University of California
San Francisco

Department of Surgery
Department of Veterans Affairs
4150 Clement Street
San Francisco, CA 94121
tel: 415/221-4810

September 2, 2014

Shuvo Roy, PhD
Professor of Bioengineering
UCSF School of Pharmacy
1700 4th Street
San Francisco, CA 94158

Dear Dr. Roy:

Thank you for inviting me to participate in your artificial kidney project as a research collaborator and consultant, providing your post-doctoral fellow, Willieford Moses, with surgical oversight and expertise.

As you know, I am a board-certified vascular surgeon holding an Associate Professorship in the Division of Vascular & Endovascular Surgery here at the University of California, San Francisco. My research is focused on exploring novel drugs and biologics designed to prevent vein graft failure and restenosis. In this capacity I am currently the principal investigator of an NIH-funded research project studying endothelial function and vein graft remodeling. As such, I have developed particular expertise in vascular remodeling after grafting which is a component of your current artificial kidney project for which I plan to serve as a research collaborator.

I will plan to work closely with Willieford Moses providing necessary oversight as he investigates the vascular conduits and technique for connecting the artificial kidney to the native blood supply. With significant experience in large animal model experiments, including ongoing experiments in a swine model, I will also plan to provide direct surgical oversight during his swine experiments and to participate when necessary in the procedures.

Having worked closely with Willieford previously in a clinical capacity as a surgical resident in training here at UCSF, I look forward to participating in his development as an academic investigator over the coming two years while he is in your biodesign laboratory.

Sincerely,

Christopher Owens, MD, MsC
Associate Professor of Vascular and Endovascular Surgery
University of California San Francisco
Chief, Division of Vascular Surgery, San Francisco VA Medical Center
Director, Vascular Integrated Physiology and Experimental
Therapeutics Laboratory Sincerely,
Tel: 415-750-2115
Email: christopher.owens@ucsfmedctr.org

University of California
San Francisco

Shant M. Vartanian, MD
Assistant Professor of Surgery
Division of Vascular and
Endovascular Surgery
400 Parnassus Ave. Room A-581
San Francisco, CA 94143-0222
415-353-4366

September 18th, 2014

Shuvo Roy, PhD
Professor of Bioengineering
UCSF School of Pharmacy
1700 4th Street
San Francisco, CA 94158

Dear Dr. Shuvo Roy,

Thank you for inviting me to serve as a consultant on the Artificial Kidney Project, assisting with the surgical considerations and technical aspects for implantation of the device. This letter is to confirm my interest in participating in your project.

I am a board-certified and fellowship-trained vascular surgeon. I am currently an Assistant Professor of Surgery in the Division of Vascular & Endovascular Division at USCF. As such I have expertise in vascular anastomotic techniques, flow dynamics and working with synthetic grafts.

In my role as a consultant on this project I will plan to work directly with Willieford Moses, providing input and recommendations regarding the surgical considerations for the implantation of the artificial kidney. We will meet regularly throughout the duration of his project and I look forward to contributing to his development as an academic surgeon.

Sincerely,

Shant Vartanian, M.D.
Assistant Professor of Surgery
Division of Vascular & Endovascular Surgery

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OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix: Dr.
First Name*: Shuvo
Middle Name:
Last Name*: Roy
Suffix: Ph.D

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ○ No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

○ Yes ○ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

Tracking Number:

Funding Opportunity Number: . Received Date:

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5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ● Project ○ Subaward/Consortium
Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 11-01-2014 **End Date*:** 04-30-2015 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Shuvo		Roy	Ph.D	PD/PI	181,500.00	0.00			0.00	0.00	0.00
2 .		Willieford		Moses		PD/PI	57,272.00	12.00			28,401.00	6,532.00	34,933.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **34,933.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
Total Number Other Personnel						**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**34,933.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: The Regents of the University of California, San Francisco

Start Date*: 11-01-2014 **End Date*:** 04-30-2015 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,000.00
2. Foreign Travel Costs	
Total Travel Cost	**1,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: The Regents of the University of California, San Francisco

Start Date*: 11-01-2014 **End Date*:** 04-30-2015 **Budget Period: 1**

F. Other Direct Costs	**Funds Requested ($)***
1. Materials and Supplies	4,478.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Dept Network Charges, CCDSS-Basic	522.00
Total Other Direct Costs	**5,000.00**

G. Direct Costs	**Funds Requested ($)***
Total Direct Costs (A thru F)	**40,933.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	**Funds Requested ($)***
1 . Modified Total Direct Cost (MTDC)	58.00	40,933.00	23,741.00
		Total Indirect Costs	**23,741.00**

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)***
Total Direct and Indirect Institutional Costs (G + H)	**64,674.00**

J. Fee	**Funds Requested ($)***

K. Budget Justification* File Name: BUDGET_JUSTIFICATION.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ● Project ○ Subaward/Consortium
Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 05-01-2015 **End Date*:** 04-30-2016 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Shuvo		Roy	Ph.D	PD/PI	181,500.00	0.00			0.00	0.00	0.00
2 .		Willieford		Moses		PD/PI	57,272.00	12.00			57,272.00	13,173.00	70,445.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **70,445.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
Total Number Other Personnel						**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**70,445.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: The Regents of the University of California, San Francisco

Start Date*: 05-01-2015 **End Date*:** 04-30-2016 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,000.00
2. Foreign Travel Costs	
Total Travel Cost	**1,000.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: The Regents of the University of California, San Francisco

Start Date*: 05-01-2015 **End Date*:** 04-30-2016 **Budget Period: 2**

F. Other Direct Costs	**Funds Requested ($)***
1. Materials and Supplies	4,478.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Dept Network Charges, CCDSS-Basic	522.00
Total Other Direct Costs	**5,000.00**

G. Direct Costs	**Funds Requested ($)***
Total Direct Costs (A thru F)	**76,445.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	**Funds Requested ($)***
1 . Modified Total Direct Cost (MTDC)	58.00	12,740.83	7,390.00
2 . Modified Total Direct Cost (MTDC)	58.50	63,704.17	37,267.00
		Total Indirect Costs	**44,657.00**

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)***
Total Direct and Indirect Institutional Costs (G + H)	**121,102.00**

J. Fee	**Funds Requested ($)***

K. Budget Justification* File Name: BUDGET_JUSTIFICATION.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**105,378.00**
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		**105,378.00**
Section C, Equipment		
Section D, Travel		**2,000.00**
1. Domestic	2,000.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**10,000.00**
1. Materials and Supplies	8,956.00	
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	1,044.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		**117,378.00**
Section H, Indirect Costs		**68,398.00**
Section I, Total Direct and Indirect Costs (G + H)		**185,776.00**
Section J, Fee		

BUDGET JUSTIFICATION

Personnel

Shuvo Roy, PhD – PI and Primary Mentor (no salary requested, effort paid from parent grant). Dr. Roy is Professor of Bioengineering and Therapeutic Sciences at UCSF, Director of The Kidney Project, and PI of the parent grant, "Biocompatibility of Implantable Renal Replacement Devices." Dr. Roy will be the candidate's primary research mentor and will provide technical expertise, engineering guidance, and oversight of the overall progress of the candidate's work described in this supplement.

Willieford Moses, MD – Diversity Candidate and Postdoctoral Research Fellow (12 calendar months per year, salary and fringe requested). Dr. Moses is a UCSF general surgery resident in his third postdoctoral year who is spending his two dedicated research years in Dr. Roy's Biodesign laboratory working to optimize the surgical implantation of the bioartificial kidney with a focus on the implantable hemofilter. Dr. Moses will be dedicated full-time to the project and will be the primary person responsible for carrying out the aims of this supplement in collaboration with the research team supported by the parent grant.

Hanmin Lee, MD – Co-mentor (effort as needed, no salary requested). Dr. Lee is Professor and Division Chief of Pediatric Surgery and leads the Department of Surgery's Innovation Training Pathway. As a co-mentor, Dr. Lee will meet monthly with Dr. Moses to review his research progress, offer surgical expertise, and provide career guidance as he progresses towards becoming a fellowship-trained academic pediatric surgeon.

John Roberts, MD – Co-mentor (effort as needed, no salary requested). Dr. Roberts is Professor and Division Chief of Transplant Surgery at UCSF. He will serve as a co-mentor to Dr. Moses, offering guidance and strategies to achieve successful surgical implantation of the hemofilter based on his expertise as a transplant surgeon. He will also provide career mentorship to Dr. Moses.

Georg Wieselthaler, MD – Consultant (effort as needed, no salary requested). Dr. Wieselthaler is Professor of Surgery and Director and Surgical Chief of Cardiac Transplantation and Mechanical Circulatory Support at UCSF. As a consultant to Dr. Moses's project, he will provide input on graft material selection and the method of anastomotic connection based on his extensive experience with artificial device implantation.

Christopher Owens, MD – Consultant (effort as needed, no salary requested). Dr. Owens is Associate Professor of Vascular and Endovascular Surgery at UCSF and Division Chief of Vascular Surgery at the San Francisco VA Medical Center. He will provide oversight and expertise to Dr. Moses as he explores the optimal vascular conduits and technique for connecting the hemofilter to the native blood supply.

Shant Vartanian, MD – Consultant (effort as needed, no salary requested). Dr. Vartanian is Assistant Professor in the Division of Vascular and Endovascular Surgery at UCSF. He will consult on strategies for connecting the hemofilter to the vasculature the based on his experience with vascular grafts in swine models.

Fringe Benefits: The following rates were used to calculate benefits requested per UCSF policy:

July 1, 2014 and forward: Postdoctoral Fellow – 23%

Supplies

Graft materials ($2,478 per year): purchase of PTFE grafts for anastomosis experiments.

Surgical supplies ($1,000 per year): includes all disposable supplies, anesthetics, analgesics, and other agents needed for animal surgeries.

Chemical reagents ($1,000 per year): includes assays for immunohistochemistry and surface analysis of hemofilter housing.

Travel

Conference attendance ($1,000 per year) Funds are requested to cover airfare and hotel for the candidate to present at one national conference per year.

Other Expenses

UCSF Data Network Recharge ($246 per year) The recharge supports the campus IT network. Per agreement by UCSF's cognizant federal agency, data network costs are an allowable direct expense. Costs are calculated monthly per FTE and pro-rated by the support provided by this grant.

UCSF ITS Desktop Recharge ($276 per year) The program provides comprehensive desktop and network support for UCSF departments on a monthly recharge basis.

Indirect Costs

The requested facilities and administrative costs reflect the on-campus indirect cost rate established by the University and the Federal government in an agreement dated May 23, 2012. The following rates were used to calculate the applicable indirect costs:

July 1, 2014 – June 30, 2015: 58.0%
July 1, 2015 and forward: 58.5%

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. First Name*: Shuvo Middle Name Last Name*: Roy Suffix: Ph.D

Position/Title*:	Professor
Organization Name*:	The Regents of the University of California, San Francisco
Department:	Bioengineering and Therapeutic
Division:	School of Pharmacy
Street1*:	1700 4th Street 203A, Box 2520
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94143-2520

Phone Number*: +1 415 514-9666 Fax Number: 415-514-9656 E-Mail*: Shuvo.Roy@ucsf.edu

Credential, e.g., agency login: shuvoroy

Project Role*: PD/PI Other Project Role Category:

Degree Type: PHD Degree Year: 2001

	File Name
Attach Biographical Sketch*:	Roy_Biosketch_2014.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Willieford Middle Name Olatoye Oluremi Last Name*: Moses Suffix: M.D.

Position/Title*: Postdoctoral Research Fellow
Organization Name*: The Regents of the University of California, San Francisco
Department: Surgery
Division: School of Medicine
Street1*: 513 Parnassus Ave, Med Sci Room S321
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0470

Phone Number*: 415 476-1239 Fax Number: E-Mail*: Willieford.Moses@ucsf.edu

Credential, e.g., agency login: WMOSES

Project Role*: Post Doctoral Other Project Role Category:

Degree Type: M.D. Degree Year: 2011

	File Name
Attach Biographical Sketch*:	Biosketch_Willieford_Moses.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Hanmin Middle Name Last Name*: Lee Suffix: M.D.

Position/Title*: Professor of Clinical Surgery
Organization Name*: The Regents of the University of California, San Francisco
Department: Surgery
Division: School of Medicine
Street1*: 513 Parnassus Ave, Room 1601
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0570

Phone Number*: +1 415 476-2538 Fax Number: E-Mail*: Hanmin.Lee@ucsfmedctr.org

Credential, e.g., agency login: LEEHANMIN

Project Role*: Other (Specify) Other Project Role Category: Mentor

Degree Type: Fellow Degree Year: 2000

	File Name
Attach Biographical Sketch*:	Bio_Lee.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Christopher Middle Name D Last Name*: Owens Suffix: M.D.

Position/Title*:	Associate Prof. In Residence
Organization Name*:	The Regents of the University of California, San Francisco
Department:	Surgery
Division:	School of Medicine
Street1*:	4150 Clement Street
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94121-0000

Phone Number*: +1 415 750-2115 Fax Number: E-Mail*: Christopher.Owens@ucsfmedctr.org

Credential, e.g., agency login: CHRIS123

Project Role*: Consultant Other Project Role Category:

Degree Type: M.Sc. Degree Year: 2007

	File Name
Attach Biographical Sketch*:	Bio_Owens.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: John Middle Name P Last Name*: Roberts Suffix: M.D.

Position/Title*:	Professor
Organization Name*:	The Regents of the University of California, San Francisco
Department:	Surgery
Division:	School of Medicine
Street1*:	400 Parnassus Ave, UC Clinics Room 730F
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94143-0780

Phone Number*: +1 415 353-9321 Fax Number: E-Mail*: John.Roberts@ucsf.edu

Credential, e.g., agency login: JRoberts

Project Role*: Other (Specify) Other Project Role Category: Mentor

Degree Type: Fellow Degree Year: 1987

	File Name
Attach Biographical Sketch*:	Bio_Roberts.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Shant Middle Name M Last Name*: Vartanian Suffix: M.D.

Position/Title*: Assistant Professor In Res
Organization Name*: The Regents of the University of California, San Francisco
Department: Surgery
Division: School of Medicine
Street1*: 400 Parnassus Ave, UC Clinics
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0222

Phone Number*: 415 353-4366 Fax Number: E-Mail*: Shant.Vartanian@ucsfmedctr.org

Credential, e.g., agency login: VARTANIAN

Project Role*: Consultant Other Project Role Category:

Degree Type: Clinical Fellow Degree Year: 2012

	File Name
Attach Biographical Sketch*:	Bio_Vartanian.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Georg Middle Name M Last Name*: Wieselthaler Suffix: M.D.

Position/Title*: Associate Prof. In Residence
Organization Name*: The Regents of the University of California, San Francisco
Department: Surgery
Division: School of Medicine
Street1*: 4150 Clement Street
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0118

Phone Number*: 415 353-8890 Fax Number: E-Mail*: Georg.Wieselthaler@ucsfmedctr.org

Credential, e.g., agency login:

Project Role*: Consultant Other Project Role Category:

Degree Type: M.D. Degree Year: 1995

	File Name
Attach Biographical Sketch*:	Bio_Wieselthaler.pdf
Attach Current & Pending Support:	

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Roy, Shuvo	**Professor**
eRA COMMONS USER NAME shuvoroy	**Bioengineering and Therapeutic Sciences**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Mount Union College Alliance, OH	BS, Magna Cum Laude, General Honors, Special Honors (Mathematics)	1992	Physics, Mathematics, and Computer Science
Case Western Reserve University Cleveland, OH	MS	1995	Electrical Engineering and Applied Physics
Case Western Reserve University Cleveland, OH	PhD	2001	Electrical Engineering and Computer Science

A. Personal Statement

Dr. Shuvo Roy will be the primary mentor for the diversity candidate in this proposal and will provide the essential mentoring, technical expertise and career guidance for a successful academic career involving surgery and bioengineering. Dr. Roy directs the Biodesign Laboratory (formerly the Biomedical Microdevices Laboratory) at UCSF and his research focuses on the development of medical devices using MEMS and related nanotechnology strategies. The areas of emphasis pertinent to this Diversity Supplement include the development of implanted medical devices, wireless sensors, and surface modification for enhanced biocompatibility. He has authored over 100 peer reviewed articles and has over 15 patents. For the past several years he has been working on the development of an implantable, bioartificial kidney to treat end stage renal disease (ESRD). Dr. Roy is a founding member of the UCSF Pediatric Device Consortium, which brings together clinical, engineering, scientific, and business innovators to focus on the development of medical devices for children. He is also co-leading UCSF's Surgical Innovations program, an interdepartmental initiative between the Departments of Surgery and Bioengineering to accelerate the translation of novel medical technologies via interdisciplinary collaboration and joint mentorship of trainees. A dedicated educator and mentor, Dr. Roy is the faculty director of the UC Berkeley-UCSF Master of Translational Medicine graduate program and a mentor to surgical residents pursuing UCSF's Innovation Training Pathway. He has developed and currently teaches a course on medical devices, diagnostics, and therapeutics and regularly lectures on the medical device design process to UCSF graduate students and to national and international academic and industry audiences. He and his lab possess all the skills, equipment and resources necessary to successfully complete this proposal.

B. Positions and Honors

Positions

1993-1998 Research Assistant, MEMS Group, Case Western Reserve University, Cleveland, OH
1998-2002 Project Staff, Department of Biomedical Engineering, Lerner The Cleveland Clinic
1998-2008 Co-Director, BioMEMS Laboratory, The Cleveland Clinic, Cleveland, OH
2001-2008 Graduate Faculty, Department of Chemical Engineering, Cleveland State University, Cleveland, OH
2001-2008 Adjunct Assistant Professor, Department of Electrical Engineering and Computer Science, Case Western Reserve University
2001-2008 Adjunct Faculty, Spine Research Laboratory, Spine Institute, The Cleveland Clinic
2002-2008 Assistant Staff, Department of Biomedical Engineering, Lerner Research Institute, The Cleveland Clinic

2005-2008 Assistant Professor, Department of Molecular Medicine, Cleveland Clinic Lerner College of Medicine (CCLCM) at Case Western Reserve University
2008-2013 Associate Professor, Department of Bioengineering and Therapeutic Sciences, UCSF
2013- Professor, Department of Bioengineering and Therapeutic Sciences, UCSF

Selected Awards and Other Professional Activities

1998 Top 40 under 40, Crain's Cleveland Business
1999 Clinical Translation Award, BioMEMS and Biomedical Nanotechnology World 2001
2003 TR 100, MIT Technology Review
2004 NASA Group Achievement – Harsh Environment MEMS
2005 Who's Who in Biotechnology, Crain's Cleveland Business
2006 Mentor Recognition Award, Cleveland Clinic Science Internship Program
2005, 2007 Cleveland Clinic Innovator
2008 Thomas G. Orr Memorial Lectureship, Southwestern Surgical Congress
2012 Nominated, UCSF Outstanding Mentorship Award
2012 Innovation Pathway Award, FDA's End Stage Renal Disease Innovation Challenge
2012 Rising Star Award, BayBio Pantheon

Patents

2002 System for Measuring Intraocular Pressure of an Eye and a MEM Sensor for Use Therewith, A.J. Fleischman, S. Roy, and H. Lewis, US Patent 6,447,449
2003 MEMS-based Integrated Magnetic Particle Identification System, A.J. Fleischman, S. Roy, M. Zborowski, and J. Chalmers, US Patent 6,623,984
2003 Miniature Ultrasound Transducer, A.J. Fleischman, S. Roy, and G. Lockwood, US Patent 6,641,540
2004 Apparatus and Method for Monitoring a Condition inside a Body Cavity, S. Roy, K. Ouriel, and A.J. Fleischman, US Patent 6,682,490
2004 Apparatus and Method for Assessing Loads on Adjacent Bones, S. Roy, L.A. Ferrara, A.J. Fleischman, and E.C. Benzel, US Patent 6,706,005
2004 Intraocular Pressure Measurement System including Sensor Mounted in a Contact Lens, A.J. Fleischman, S. Roy, and H. Lewis, US Patent 6,749,568
2004 Microneedle Array Module and Method of Fabricating the Same, S. Roy and A.J. Fleischman, US Patent 6,790,372
2006 Apparatus and Method for Measuring Intraocular Pressure, A.J. Fleischman and S. Roy, US Patent 6,994,672
2006 Ultrafiltration Membrane, Device, Bioartificial Organ, and Methods, W.H. Fissell, H.D. Humes, S. Roy, and A.J. Fleischman, US Patent 7,048,856
2007 Intraocular Pressure Measurement System including a Sensor Mounted in a Contact Lens, A.J. Fleischman, S. Roy, and H. Lewis, US Patent 7,169,106
2007 Apparatus and Method for Assessing Loads on Adjacent Bones, S. Roy, L.A. Ferrara, A.J. Fleischman, and E.C. Benzel, US Patent 7,182,736
2007 Microneedle Array Module and Method of Fabricating the Same, S. Roy and A.J. Fleischman, US Patent 7,262,068
2007 Method and Apparatus for In Vivo Sensing, A.J. Fleischman, S. Roy, and J. Talman, US Patent 7,284,442
2009 Apparatus and method for assessing loads on adjacent bones, S. Roy, A.J. Fleischman, E.C. Benzel, and L.A. Ferrara, US Patent 7,491,179
2009 Ultrafiltration Membrane, Device, Bioartificial Organ, and Methods, W.H. Fissell, H.D. Humes, S. Roy, and A.J. Fleischman, US Patent 7,540,963
2010 Method and apparatus for eddy current compensation in a radio frequency probe, J.R. Talman, A.J. Fleischman, B.L. Sauer, S. Roy, US Patent 7,771,351
2011 Method and apparatus for determining a characteristic of an in vivo sensor. J.R. Talman, S. Roy, B.L. Sauer, A.J. Fleischman, US Patent 7,878,208B.

C. Selected Publications

1. Fissell WH, Dubnisheva A, Eldridge AN, Fleischman AJ, Zydney AL, Roy S. High-performance silicon nanopore hemofiltration membranes. Journal of Membrane Science 2009;326(1):58-63. PMCID: 2607036
2. Fissell WH, Hofmann CL, Ferrell N, Schnell L, Dubnisheva A, Zydney AL, Yurchenco PD, Roy S. Solute Partitioning and Filtration by Extracellular Matrices. Am J Physiol Renal Physiol 2009. PMCID: 2775571
3. Fissell WH, Roy S. The implantable artificial kidney. Semin Dial 2009;22(6):665-70.
4. Datta S, Conlisk AT, Kanani DM, Zydney AL, Fissell WH, Roy S. Characterizing the surface charge of synthetic nanomembranes by the streaming potential method. J Colloid Interface Sci. 2010;348(1):85-95. PMCID: 2900191
5. Li L, Marchant RE, Dubnisheva A, Roy S, Fissell WH. Anti-biofouling Sulfobetaine Polymer Thin Films on Silicon and Silicon Nanopore Membranes. J Biomater Sci Polym Ed. 2010. PMID: 20546677
6. Melvin ME, Fissell WH, Roy S, Brown DL. Silicon induces minimal thromboinflammatory response during 28-day intravascular implant testing. ASAIO J. 2010;56(4):344-8. PMID: 20431483
7. Kanani DM, Fissell WH, Roy S, Dubnisheva A, Fleischman A, Zydney AL. Permeability - Selectivity Analysis for Ultrafiltration: Effect of Pore Geometry. J Memb Sci. 2010;349(1-2):405. PMCID: 2821117
8. Ferrell N, Desai RR, Fleischman AJ, Roy S, Humes HD, Fissell WH. A microfluidic bioreactor with integrated transepithelial electrical resistance (TEER) measurement electrodes for evaluation of renal epithelial cells. Biotechnol Bioeng. 2010. PMCID: 3903011
9. Muthusubramaniam L, Lowe R, Fissell WH, Li L, Marchant RE, Desai TA, Roy S. Hemocompatibility of silicon-based substrates for biomedical implant applications. Ann Biomed Eng. 2011;39(4):1296-305. PMCID: 3069312
10. Roy S. Goldman K. Marchant R. Zydney A. Brown D. Fleischman A. Conlisk A. Desai T. Duffy S. Humes H. Fissell W. Implanted renal replacement for end-stage renal disease. Panminerva Medica. 2011: 53(3):155-66. PMID: 21775942

D. Research Support

Ongoing Research Support

UC Research Opportunity Funds 01/01/2013-12/31/2014
UC Biodevice Innovation Initiative for Eliminating Never Events
The goal of this proposal is to support the establishment of a new cross-campus research initiative to design innovative solutions to never events, which, once developed, can be implemented system-wide across the UC medical centers.
Role on Project: Principal Investigator

Rogers Bridging the Gap Award 02/01/2012-12/31/2014
California Institute for Quantitative Biosciences
Intravascular Capsule for Treatment of Type I Diabetes
The goal of this project is to use silicon nanopore membranes (SNM) to develop an intravascular capsule that will immunoisolate donor pancreatic islets for the treatment of Type I diabetes.
Role on Project: Principal Investigator

UCOP Proof of Concept Award 06/01/2013-05/31/2015
Silicon Dialyzer Prototype
This project will optimize a low-hydraulic resistance cartridge to house SNM and demonstrate its utility for toxin clearance without the need for blood pumps in pigs.
Role on Project: Principal Investigator

2 P50 FD003793-05 (PI: Harrison) 09/25/2009-08/31/2015
FDA
UCSF Pediatric Device Consortium

The mission of the UCSF Pediatric Device Consortium is to provide the infrastructure, expertise, and resources for device development to innovators seeking to solve urgent pediatric clinical problems by designing and developing novel medical devices.
Role on Project: Co-PI

NSF 1319268 (PI: Harrison) 08/01/2013-07/31/2015
National Science Foundation Partnerships for Innovation: Building Innovation Capacity Program
Biomimetic Sealant for Aqueous Environments
This project will focus on completing the early translational research tasks (in vivo efficacy and biocompatibility demonstrations; optimization of glue chemistry and formulation for mass-production) to advance development of a novel biocompatible glue toward medical use as a surgical sealant that works in wet conditions.
Role on Project: Co-PI

1R01 EB014315 (Roy) 05/01/2012-04/30/2016
NIH
Biocompatibility of Implantable Renal Replacement Devices
The goal of this project is to better understand the blood-device interactions spanning across anatomic, histologic, and molecular length scales and their influence on hemofilter biocompatibility.
Role on Project: Principal Investigator

NSF 00008008 (Roy) 08/15/2012-07/31/2016
UC Berkeley Prime
Flexible Resorbable Organic and Nanomaterial Therapeutic Systems
For this project the UCSF team will provide guidance on device design and materials selection including biocompatibility.
Role on Project: Co-PI

1R01EB012031-01A1 (PI: Hetts) 08/01/2011- 05/31/2015
NIBIB/NIH
Endovascular Magnetic Catheter for Interventional MRI
The major goal of this project is to develop a steerable catheter for minimally invasive targeted therapy of aneurysms and tumors.
Role on Project: Co-Investigator

P50AR060752 (PI: Majumdar/Lane) 04/01/2011-03/31/2016
NIH/NIAMS
Translation of Quantitative Imaging in Osteoarthritis
The major goal of this project is to establish core facilities to support NIH-funded investigators
Role on Project: Co-Investigator (8/1/12-3/31/16)

LANL (UCSF Subaward) 10/01/2012-09/30/2017
Integration of Novel Technologies for Organ Development and
Rapid Assessment of Medical Countermeasures (INTO-RAM)
This project focuses on the development of an organ microsystem representative of kidney physiology to investigate kidney-lung cross-talk in disease states and evaluation of drug efficacy and toxicity.
Role on Project: Co-PI

Gates Foundation 01/01/2014-12/31/2018
A "Smart Diaphragm" for the Early Detection of Preterm Labor
This project will develop a vaginal diaphragm to detect changes in cervical collagen and wirelessly alert health providers before preterm labor begins.
Role on Project : Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Moses, Willieford Olatoye Oluremi	General Surgery Resident, Post-Graduate-Year 4; Postdoctoral Research Fellow
eRA COMMONS USER NAME (credential, e.g., agency login) WMOSES	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Duke University, Durham, North Carolina	B.S.	05/06	Psychology (Major) Chemistry (Minor)
University of California, San Francisco	M.D.	06/11	Medicine
University of California, San Francisco		06/11-	General Surgery Resident

A. Personal Statement

Since my time as a medical student I have had a strong interest in academic medicine, specifically translational research and the concept of bridging bench-work with the clinical setting. Working closely with my PI and mentor Dr. Electron Kebebew (formerly Professor of Surgery at UCSF, now Director of the Endocrine Branch of Surgery at the National Cancer Institute), this interest initially took the form of bench-top research establishing the correlation of various genetic alterations with aggressive forms of papillary thyroid cancer. With time, this research evolved into determining the clinical utility of prospectively testing for these somatic mutations to help guide clinical decision-making regarding the need for aggressive surgical resection versus less morbid intervention. Through my involvement in this project, I witnessed basic science traverse into the clinical realm to directly affect clinical care. The opportunity to extend this research in Uganda during a summer project documenting thyroid cancer at their national hospital solidified my interest in learning to directly translate basic science theory into clinical practice and applying it on the global scale.

As a surgeon in training, I am fortunate to have the opportunity to profoundly impact the way care is delivered by bridging the gap between basic science and clinical practice through innovation. The very backbone of the field of surgery stands upon earnest attempts to make possible seemingly radical approaches to the treatment of unmet clinical problems. This realization led me to my current project in Dr. Shuvo Roy's Biodesign Laboratory at UCSF, in which end stage renal disease now appears surmountable through device innovation and the translation of basic science into clinical practice. Through this project I seek to establish the necessary tools to eventually lead my own investigations as an academic surgeon developing solutions to the clinical problems that I will face in the operating room. I plan to achieve this over the next two years through collaboration with biomedical engineers, biologists and chemists; course-work on biostatistics, device innovation, and scientific writing; learning to conduct animal-model experiments; and mentorship from prominent faculty within the UCSF Department of Surgery who have each contributed significantly to the development of new approaches to surgical care and the devices necessary to achieve them. Working with Dr. Roy on the artificial kidney project will greatly enhance my understanding of translational research and device innovation and prepare me for my own investigations in academic medicine.

B. Positions and Honors

Positions

2007-2009 Medical Student Research Assistant, University of California, San Francisco
2011-2012 Intern, Department of Surgery, University of California, San Francisco
2012- Resident, Department of Surgery, University of California, San Francisco
2014- Postdoctoral Research Fellow, Biodesign Laboratory, University of California, San Francisco

Honors

2007 Dean's Research Fellowship, School of Medicine, UCSF
2008 Dean's Research Fellowship, School of Medicine, UCSF
2011 Steinhardt Award, School of Medicine, UCSF
2012 Medical Student Teaching Award, Department of Surgery, UCSF
2014 Alpha Omega Alpha Honor Medical Society, Inductee, UCSF Chapter

C. Selected Peer-Reviewed Publications

1. Fualal J, **Moses W**, Jayaraman S, Nalugo M, Ozgediz D, Duh Q, Gosnell J, Kebebew E. Characterizing Thyroid Disease and Identifying Barriers to Care and Treatment in Uganda. *World J Endoc Surg* 2012;4:47-53.
2. **Moses W**, Weng J, Kebebew E. Prevalence, clinicopathologic features and somatic genetic mutation profile in hereditary versus sporadic non-medullary thyroid cancer. *Thyroid.* 2011;21:367-371.
3. Vriens MR, **Moses W**, Weng J, Peng M, Griffin A, Bleyer A, Pollock B, Indelicato D, Hwang J, Kebebew E. Clinical and molecular features of papillary thyroid cancer in adolescents and young adults. *Cancer.* 2011;117:259-267.
4. Mathur A, **Moses W**, Khanafshar E, Rahbari R, Duh Q, Clark O, Kebebew E. Higher rate of BRAF mutation in papillary thyroid cancer over time: a single-institution study. *Cancer*. 2011;117:4390-5.
5. **Moses W**, Weng J, Sansano I, Peng M, Khanafshar E, Ljung B, Duh Q, Clark O, Kebebew E. Molecular testing for somatic mutations improves the accuracy of thyroid fine needle aspiration biopsy. *World Journal of Surgery.* 2010;34:2589-2594.
6. Mathur A, Weng J, **Moses W**, Steinberg S, Rahbari R, Kitano M, Khanafshar E, Ljung B, Duh Q, Clark O, Kebebew E. A prospective study evaluating the accuracy of using combined clinical factors and candidate diagnostic markers to refine the accuracy of thyroid fine needle aspiration biopsy. *Surgery.* 2010;148:1170-1176.
7. **Moses W**, Weng J, Khanafshar E, Duh QY, Clark OH, Kebebew E. Multiple Genetic Alterations in Papillary Thyroid Cancer are Associated with Younger Age at Presentation. *J Surg Res*. 2010;160:179-183.
8. Vriens MR, Suh I, **Moses W**, Kebebew E . Clinical features and genetic predisposition to hereditary nonmedullary thyroid cancer. *Thyroid*. 2009;19:1343-1349.

D. Research Support

None Presently

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Hanmin Lee, MD	Professor of Surgery, Pediatrics, and Obstetrics, Gynecology & Reproductive Sciences Chief, Division of Pediatric Surgery Director, UCSF Fetal Treatment Center Surgeon-in-chief, UCSF Benioff Children's Hospital
eRA COMMONS USER NAME LEEHANMIN	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Johns Hopkins University	B.A.	1983-87	Biology
New York University School of Medicine	M.D.	1987-91	Medicine
New York University School of Medicine	Resident	1991-94	Surgery
Harvard University	Postdoctoral Fellow	1994-96	Tissue Engineering
New York University School of Medicine	Senior Resident	1996-97	Surgery
New York University School of Medicine	Chief Resident	1997-98	Surgery
Emory University	Fellow	1998-00	Pediatric Surgery

A. Personal Statement

I am a pediatric and fetal surgeon who is only the second director of the Fetal Treatment Center in its 25+ year history. My clinical interests include neonatal surgery, fetal surgery, minimally invasive surgery, and biliary surgery. My research interests include tissue engineering, proteomic assessment of maternal-fetal diseases, integration of emerging technologies into clinical surgery, and developing innovative devices to improve patient safety. I enjoy international recognition as a leader in fetal surgery and pediatric minimally invasive surgery, having given numerous national and international talks. I have been a principal investigator or co-investigator on a number of fetal surgery and minimally invasive surgical trials. I am also leading a new effort in device innovation in the Department of Surgery to promote and support medical technology innovations coming from the department's surgeons as well as spearheading development of an innovation-focused training program and curriculum for surgical residents.

B. Positions and Honors

Positions and Employment

2000-2005 Assistant Professor of Surgery, University of California, San Francisco School of Medicine
2001-2005 Assistant Professor of Pediatrics and OB/GYN & Reproductive Sciences (WOS), UCSF
2006-2011 Associate Professor In Residence of Surgery, UCSF
2006-2011 Associate Professor In Residence of Pediatrics and OB/GYN (WOS), UCSF
2011 – Present Professor of Clinical Surgery, UCSF
2011 – Present Professor of Pediatrics and OB/GYN & Reproductive Sciences (WOS), UCSF

Other Experience and Professional Memberships

2001-Present Program Committee, International Pediatric Endosurgery Group (IPEG)
2001-Present Outcomes Committee, IPEG
2002-Present Fetal Surgery Committee, American Pediatric Surgical Association (APSA)
2003-Present Course Director, Advanced Training Techniques in Minimally Invasive Pediatric Surgery, APSA
2005-Present Steering Committee, North American Fetal Treatment Network
2006 Invited Panelist, IPEG
2006 Program Director, International Fetal Surgery and Medicine Society
2006-Present Endosurgery Committee, APSA
2007-Present Vice Chair, Fetal Therapy Committee, APSA

2006-Present	Director, Fetal Treatment Center, UCSF Medical Center and Benioff Children's Hospital
2011-Present	Chief, Division of Pediatric Surgery, UCSF Medical Center and Benioff Children's Hospital
2012-Present	Surgeon-in-chief, UCSF Benioff Children's Hospital

Honors

1998	Theodore Barnett Award for Outstanding Chief Surgical Resident Educator, New York University Medical School
2006	Robert Touloukian Visiting Professor, Yale University Medical Center
2008	Invited Keynote Speaker, National Workshop of Pediatric Laparoscopy, 3rd Annual Conference of the Pediatric Endo Surgeons of India
2010	Gerald Zwiren Pediatric Surgery Visiting Professorship, Emory University School of Medicine
2010	Visiting Professor, University of Texas, Houston
2010	Jack Harburg Visiting Professor, Baylor University
2010	Invited Visiting Professor, Vanderbilt University
2011	Invited Visiting Professor, John Fangman Award
2012	Exceptional Physician Award, UCSF Medical Center

C. Selected Peer-reviewed Publications (in chronological order).

1. Kurpinski KT, T Stephenson J, Janairo RR, Lee H, Li S. The effect of fiber alignment and heparin coating on cell infiltration into nanofibrous PLLA scaffolds. Biomaterials 2010;31(13):3536-42. Epub 2010 Feb 1.
2. Jelin E, Hirose S, Rand L, Curran P, Feldstein V, Guevara-Gallardo S, Jelin A, Gonzales K, Goldstein R, Lee H. Perinatal outcome of conservative management versus fetal intervention for twin reversed arterial perfusion sequence with a small acardiac twin. Fetal Diagn Ther 2010;27(3):138-41. Epub 2010 Mar 9.
3. Adzick NS, Thom EA, Spong CY, Brock JW 3rd, Burrows PK, Johnson MP, Howell LJ, Farrell JA, Dabrowiak ME, Sutton LN, Gupta N, Tulipan NB, D'Alton ME, Farmer DL; MOMS Investigators. A randomized trial of prenatal versus postnatal repair of myelomeningocele. N Engl J Med 2011;364(11):993-1004. Epub 2011 Feb 9.
4. Superina R, Magee JC, Brandt ML, Healey PJ, Tiao G, Ryckman F, Karrer FM, IYer K, Fecteau A, West K, Burns RC, Flake Alee H, Lowell JA, Dillon P, Colombani P, Ricketts R, Li Y, Moore J, Wang KS, Childhood Liver Disease Research and Education Network. The anatomic pattern of biliary atresia identified at time of Kasai hepatoportoenterostomy and early postoperative clearance of jaundice are significant predictors of transplant-free survival. Ann Surg. 2011 Oct;254(4):577-85.
5. Jelin EB, Schecter SC, Gonzales KD, Hirose S, Lee H, Machin GA, Rand L, Felstein VA. Guide wire assisted catheterization and colored dye injection for vascular mapping of monochorionic twin placentas. J Vis Exp. 2011 Sep 5;(55):e2837. Doi: 10.3791/2837.
6. Byrne FA, Lee H, Kipps AK, Brook MM, Moon-Grady AJ. Echocardiographic risk stratification of fetuses with sacrococcygeal teratoma and twin-reversed arterial perfusion. Fetal Diagn Ther. 2011;30(4):280-8. Epub 2011 Nov 12.
7. Loh KC, Jelin E, Hirose S, Felstein V, Goldstein R, Lee H. Microcystic congenital pulmonary airway malformation with hydrops fetalis: steroids vs open fetal resection. J Pediatr Surg. 2012 Jan;47(1):36-9.
8. Saadai P, Lee TH, Bautista G, Gonzales KD, Nijagal A, Busch MP, Kim CJ, Romero R, Lee H, Hirose S, Rand L, Miniati D, Farmer DL, Mackenzie TC. Alterations in maternal-fetal cellular trafficking after fetal surgery. J Pediatr Surg. 2012 Jun;47(6):1089-94.
9. Saadai P, Jelin EB, Nijagal A, Schecter SC, Hirose S, Mackenzie TC, Rand L, Goldstein R, Farrell J, Harrison M, Lee H. Long-term outcomes after fetal therapy for congenital high airway obstructive syndrome. J Pediatr Surg. 2012 Jun;47(6):1095-100.
10. Norton ME, Brar H, Weiss J, Karimi A, Laurent LC, Caughey AB, Rodriguez MH, Williams J 3rd, Mitchell ME, Adair CD, Lee H, Jacobsson B, Tomlinson MW, Oepkes D, Hollemon D, Sparks AB, Oliphant A, Song K. Non-Invasive Chromosomal Evaluation (NICE) Study: results of a multicenter prospective cohort study for detection of fetal trisomy 21 and trisomy 18. Am J Obstet Gynecol. 2012 Aug;207(2):137.e1-8.
11. Lee H, Bebbington M, Crombleholme TM; North American Fetal Therapy Network. The North American Fetal Therapy Network Registry data on outcomes of radiofrequency ablation for twin-reversed arterial perfusion sequence. Fetal Diagn Ther. 2013;33(4):224-9.

12. Shue E, Bolouri M, Jelin EB, Vu L, Bratton B, Cedars E, Yoke L, Byrne F, Hirose S, Feldstein V, Miniati D, Lee H. Tumor metrics and morphology predict poor prognosis in prenatally diagnosed sacrococcygeal teratoma: a 25-year experience at a single institution. J Pediatr Surg. 2013 Jun;48(6):1225-31.
13. Chung P, Rowe A, Etemadi M, Lee H, Roy S. Fabric-based pressure sensor array for decubitus ulcer monitoring. Conf Proc IEEE Eng Med Biol Soc. 2013;2013:6506-9.
14. Derderian SC, Iqbal CW, Goldstein R, Lee H, Hirose S. Fetoscopic approach to amniotic band syndrome. J Pediatr Surg. 2014 Feb;49(2):359-62.
15. Vu LT, Vittinghoff E, Nobuhara KK, Farmer DL, Lee H. Surgical site infections in neonates and infants: is antibiotic prophylaxis needed for longer than 24 h? Pediatr Surg Int. 2014 Jun;30(6):587-92.

D. Research Support

Current Research Support

Pilot funding — Lee H (PI) — 07/11/14 – 9/30/14
University of California Office of the President
Hospital Acquired Pressure Ulcers
This is pilot funding from the University of California Office of the President to develop a project plan to address and mitigate the problem of hospital-acquired pressure ulcers at all UC Health medical centers, with the goal of receiving follow-on funding to execute the full project upon completion of a compelling plan.
Role: PI

Catalyst Award — Lee H (PI) — 03/10/14 – 06/30/15
UCSF Clinical and Translational Science Institute
SmartDerm: A Monitoring System for Decubitus Ulcer Prevention
This award will fund the continued development and testing of the SmartDerm sensor technology and risk algorithm. The SmartDerm device is a novel pressure-sensitive wound dressing for decubitus ulcer monitoring and prevention.
Role: PI

Research Opportunity Funds — Roy S (PI) — 01/01/13 – 12/31/14
University of California Office of the President
UC Biodevice Innovation Initiative for Eliminating Never Events
This award provides start-up funding to establish a new cross-campus research initiative to design innovative, device-based solutions to preventable hospital-acquired conditions, or never events.
Role: Co-PI

Pilot funding — Lee H (PI) — 07/01/12 – 06/30/15
Dean's Fund at Mount Zion
Mount Zion Biodevice Innovation Program
This grant provides initial support for a new translational research training program based at the UCSF Mount Zion campus for surgical residents interested in clinical innovation.
Role: PI

5 U01 HD68541-02 — Thom E (PI) — 07/01/11 – 06/30/16
NIH/NICHD
A Follow-up of Children Enrolled in the Management of Myelomeningocele Study (MOMS II)
MOMS 2 is a follow-up study of the children from the Management of Myelomeningocele Study (MOMS).
Role: PI, UCSF site

Completed Research Support (last 3 years)

Catalyst Pilot Award — Lee H (PI) — 12/18/13 – 06/30/14
UCSF Clinical and Translational Science Institute
SmartDerm
This pilot award is funding device prototyping, iOS development, and database analysis to get the SmartDerm device, a novel pressure sensitive wound dressing for decubitus ulcer monitoring, ready for initial testing in patients.

Role: PI

Research Opportunity Funds Rand L (PI) 08/01/12 – 07/31/14
University of California Office of the President
UC Consortium for Fetal and Neonatal Care
The aim of this grant is to convene a multidisciplinary group of fetal experts from the five UC medical centers to create a new UC system-wide organizational paradigm focused on enhancing research opportunities, training, and clinical care in fetal medicine.
Role: Co-I

UCSF Research Allocation Program Lee H (PI) 02/01/2013-01/31/2014
Multidisciplinary Research Project Planning category
Educational Planning Grant: UCSF Biodevice Innovation Program
These funds will be used to create a new multidisciplinary research training program focused on clinical and translational innovation.
Role on Project: PI

5 U01DK062500 Rosenthal P (PI) 09/15/02 – 05/31/14
NIH/National Institute of Diabetes and Digestive and Kidney Disease
Childhood Liver Disease Research and Education Network
This proposal brings together a unique consortium of investigators and resources within the State of California with a plan for a participating Clinical Center in the Childhood Liver Disease Research and Education Network. Our research plan describes the establishment of a large multicomponent Clinical Center patient database that would contribute to the proposed multicenter Childhood Liver Disease Research and Education Network.
Role: Co-I

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
OWENS, CHRISTOPHER DEAN	Associate Professor In Residence
eRA COMMONS USER NAME (credential, e.g., agency login) CHRIS123	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Indiana University	B.S.	06/90	Chemistry/Biology
Indiana University School of Medicine	M.D.	06/98	
Harvard Medical School	Fellow	06/06	Surgery
Brigham and Women's Hospital (Beth Israel Deaconess Medical Center	Resident	06/03	General Surgery
Brigham and Women's Hospital	Resident	06/03	General Surgery
St. Elizabeth's Medical Center	Fellow	06/04	Vascular Medicine and Endovascular Surgery
Brigham and Women's Hospital	Fellow	06/06	Vascular and Endovascular Surgery
Harvard Medical School	M.Sc.	06/07	

A. Personal Statement

Dr. Christopher D. Owens is the director of the Vascular Integrated Physiology and Experimental Therapeutics (VIPERx) core laboratory. Physically located at the San Francisco VA Medical Center (1C9), the VIPERx laboratory is a multi-specialty core lab investigating basic principles of vascular physiology and healing as they relate to diverse pathologies such as peripheral artery disease, chronic kidney disease, arterio-venous fistula (AVF) maturation, and arterial intervention. We investigate vascular structure and function through high-resolution MRI, computational fluid dynamics, vascular duplex ultrasound and intravascular ultrasound coupled with post-processing software. We commonly employ both approved and investigational new drugs and devices to probe mechanisms of vascular structure and function in animal models and early phase human studies. Dr. Owens has been involved in translational research investigating hemodynamic regulation of vascular remodeling and biomarker discovery for the past 10 years. This work has been supported by both extramural and intramural funding mechanisms. My research takes a mechanistic approach to vascular physiology, particularly the adaptation in arterial environment and healing following peripheral intervention. Over the past ten years, I have developed a broad background in vascular physiology and pharmacologic approaches to interrogate vascular structure which will be key to the present application. I am the national principal investigator of the Dexamethasone to the Adventitia to eNhance Clinical Efficacy (DANCE) study which is a prospective, core lab adjudicated, single-arm study with a targeted enrolment of 300 patients at 30 US sites. I am also PI of 2 investigational new drugs delivered locally to improve outcomes following angioplasty, PRT-201 (in phase 1 currently) and Nab-rapamycin. I have been the lead PI of 2 first-in-man clinical studies testing novel devices for the treatment of PAD.

B. Positions and Honors

Positions and Employment

2006-2008 Instructor, Surgery, Harvard Medical School
2006-2008 Clinical Associate, Surgery, Brigham and Women's Hospital
2007-2008 Staff Surgeon, Surgery, West Roxbury Veterans Affairs Hospital
2008-present Associate Professor, Surgery, University of California, San Francisco
2008-present Attending Surgeon, Surgery, Veterans Affairs Medical Center - San Francisco

2008-present Active Surgical Staff, Surgery, UCSF Medical Center
2012-present Active Surgical Staff, Surgery, San Francisco General Hospital
2013-present Courtesy Surgical Staff, Surgery, St. Mary's Medical Center
2014-present Chief, Vascular Surgery, Veterans Affairs Medical Center - San Francisco

Other Experience and Professional Memberships

2007-present American Registry for Diagnostic Medical Sonography
2009-present Society for Vascular Surgery
2009-present American Heart Association and American Stroke Association
2009-present UCSF Institute for Molecular Medicine
2010-present Association for Academic Surgery
2012-present American Association for the Advancement of Sciences
2012-present Western Vascular Society
2013-present Northern California Vascular Society
2014-2017 Council on Peripheral Vascular Disease, American Heart Association
2014-present Society for Vascular Medicine

Honors

1994 Scholarship, American Medical Association
1995 Scholarship, American Medical Association
1995 William J. Rosenbower Scholarship, Indiana University School of Medicine
1995 Research Training Fellowship for Medical Students, Howard Hughes Medical Institute
1996 Van Nuys Fellowship, Indiana University School of Medicine
1996 Alpha Omega Alpha, Indiana University School of Medicine
1997 Medical Student Award, American College of Surgeons
2006 Clement Darling Award for Excellence in Clinical Research on Vascular Disease, New England Society for Vascular Surgery
2008 NHLBI/Lifeline Award, American Vascular Association
2011 First Place Basic Science Poster, Society for Vascular Surgery Annual Meeting, Chicago, IL

C. Selected Peer-Reviewed Publications

1. Mitsouras D, Mulkern RV, Owens CD, Conte MS, Ersoy H, Luu TM, Whitmore AG, Creager MA, Rybicki FJ. High-resolution peripheral vein bypass graft wall studies using high sampling efficiency inner volume 3D FSE. Magn Reson Med, 2008 Mar;59(3):650-4.
2. Rybicki FJ, Mitsouras D, Owens CD, Whitmore AG, Ersoy H, Mulkern RV, Creager MA, Conte MS. Lower Extremity Peripheral Vein Bypass Graft Wall Thickness Changes Demonstrated 1 and 6 Months After Surgery With Ultra-High Spatial Resolution Black Blood Inner Volume Three-Dimensional Fast Spin Echo Magnetic Resonance Imaging. Int J Cardiovasc Imaging, 2008 Jun;24(5):529-33.
3. Owens CD, Wake N, Conte MS, Gerhard-Herman M, Beckman JA. In vivo human lower extremity saphenous vein bypass grafts manifest flow mediated vasodilation. J Vasc Surg, 2009 Nov;50(5):1063-70.
4. Rybicki FJ, Mitsouras D, Owens CD, Whitmore A, Gerhard-Herman M, Wake N, Cai T, Zhou Q, Conte MS, Creager MA, Mulkern RV. Multi-contrast high spatial resolution black blood inner volume three-dimensional fast spin echo MR imaging in peripheral vein bypass grafts. Int J Cardiovasc Imaging, 2010 Aug;26(6):683-91.
5. Ho KJ, Spite M, Owens CD, Lancero H, Kroemer AH, Pande R, Creager MA, Serhan CN, Conte MS. Aspirin-triggered lipoxin and resolvin E1 modulate vascular smooth muscle phenotype and correlate with peripheral atherosclerosis. Am J Pathol, 2010 Oct;177(4):2116-23.
6. Owens CD, Wake N, Kim JM, Hentschel D, Conte MS, Schanzer A. Endothelial function predicts positive arterial-venous fistula remodeling in subjects with stage IV and V chronic kidney disease. J Vasc Access, 2010 Oct-Dec;11(4):329-34.
7. Owens CD, Hevelone, N, Kim JM, Belkin M, Creager MA, Gasper W, Conte MS. An integrated biochemical prediction model of all-cause mortality in patients undergoing lower extremity bypass surgery for advanced peripheral artery disease. J Vasc Surg. 2012 Sept; 56(3)686-695.

8. Sigovan M, Owens CD, Alley H, Gasper WJ, Saloner D. USPIO-enhanced MRA of Arterio-Venous Fistulas in Patients with Renal Failure. Radiology.2012 Nov. 265(2)584-590.
9. Gasper WJ, Owens CD, Kim JM, Hills N, Belkin M, Creager MA, Conte MS. Early (30-day) vein remodeling is predictive of midterm graft patency after lower extremity bypass. J Vasc Surg. 2013 Jan;57(1):9-18. doi: 10.1016/j.jvs.2012.06.098. Epub 2012 Sep 7.
10. Sigovan M, Rayz V, Gasper W, Alley HF, Owens CD, Saloner D. Vascular Remodeling in Autogenous Arterio-Venous Fistulas by MRI and CFD. . Ann Biomed Eng. 2013 Apr;41(4):657-68. doi: 10.1007/s10439-012-0703-4. Epub 2012 Nov 27.
11. Conte MS, Owens CD, Belkin M, Creager MA, Edwards KL, Gasper WJ, Kenagy RD, Leboeuf RC, Sobel M, Clowes A. A single nucleotide polymorphism in the p27 (Kip1) gene is associated with primary patency of lower extremity vein bypass grafts. J Vasc Surg. 2013 May;57(5):1179-85.e1-2. doi: 10.1016/j.jvs.2012.11.040. Epub 2013 Jan 9.
12. Owens CD, Gasper WJ, Rahman AS, Conte MS. Vein graft failure. J Vasc Surg. 2013 Oct 3. doi:pii: S0741-5214(13)01531-0. 10.1016/j.jvs.2013.08.019. [Epub ahead of print]
13. Gasper WJ, Jimenez CA, Walker J, Conte MS, Seward K, Owens CD. Adventitial Nab-Rapamycin Injection Reduces Porcine Femoral Artery Luminal Stenosis Induced by Balloon Angioplasty via Inhibition of Medial Proliferation and Adventitial Inflammation.Circ Cardiovasc Interv. 2013 Nov 12. [Epub ahead of print]
14. Grenon SM, Chong K, Alley H, Nosova E, Gasper W, Hiramoto J, Boscardin WJ, Owens CD. Walking disability in patients with peripheral artery disease is associated with arterial endothelial function. J Vasc Surg. 2014 Apr;59(4):1025-34. doi: 10.1016/j.jvs.2013.10.084. Epub 2014 Jan
15. Owens CD, Gasper WJ, Walker JP, Alley HF, Conte MS, Grenon SM. Safety and feasibility of adjunctive dexamethasone infusion into the adventitia of the femoropopliteal artery following endovascular revascularization. J Vasc Surg. 2014 Apr;59(4):1016-24.

D. Research Support

On-going Research Support

2R44HL102998-02 Owens (PI) 07/15/2013-04/30/2015
NIH/NHLBI
Improved Adventitial Rapamycin Therapy for Peripheral Artery Restenosis
The major goals of this project are to assist and execute the clinical protocol by preparing the FDA submission, writing the phase A and B protocols, and preparing the CRFs for this project.
Role: Co-Principal Investigator

U01HL107407 Menard (PI) 04/01/2015-03/31/2020
NIH/NHLBI
Randomized, Multicenter, Controlled Trial to Compare Best Endovascular versus Best Surgical Therapy in Patients with Critical Limb Ischemia (BEST-CLI)
This proposal will investigate the links between ischemia- and inflammation-mediated vascular stress biomarkers (GDF15, FSTL1, VEGF-A165b, VEGF-A165a, Wnt5a, SFRP5) and advanced PAD by performing serial measurements in 500 patients with CLI enrolled in the Best endovascular or best open surgical treatment (BEST) trial at baseline, 30 days and 6 months.
Role: Co-Investigator

Completed Research Support

REAC Pilot Research Award, University of California, San Francisco Owens (PI) 07/01/2010-06/30/2012
Endothelial Function and Arterio-venous Fistula Maturation
This longitudinal observational pilot study has been designed to elucidate biomechanical, functional, and biochemical factors involved in arterio-venous fistula remodeling and maturation.
Role: Principal Investigator

1R43HL102998-01 Seward (PI) 09/01/2010-08/31/2012
NIH/NHLBI
Improved Adventitial Sirolimus Therapy for Peripheral Artery Restenosis: A Preclinical Study (Phase II)

The major goals of this project are to assess the magnitude of effect, study the pharmacokinetics, and determine toxic effects and pivotal efficacy of a nanoparticle-albumin-bound sirolimus in the treatment of peripheral artery disease.
Role: Co-Investigator

K23 HL92163 Owens (PI) 09/15/2008-07/31/2013
NIH/NHLBI
Endothelial Function and Vein Graft Remodeling
This is a prospective study to evaluate the relationship between endothelial function and vein graft remodeling in human subjects
Role: Principal Investigator

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
John P. Roberts, M.D.	Professor of Surgery Chief, Division of Transplant
eRA COMMONS USER NAME (credential, e.g., agency login) JRoberts	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Stanford University, Palo Alto, CA	B.S.	1976	Biology
University of California, San Diego, CA	M.D.	1980	Medicine
University of Washington, Seattle, WA	Resident	1980-1983	Surgery
Cornell University, New York, NY	Research Fellow	1983-1985	Surgery
University of Washington, Seattle, WA	Resident	1985-1986	Surgery
University of Minnesota, Minneapolis, MN	Fellow	1986-1987	Transplant

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

A. PERSONAL STATEMENT:

I currently serve as the Chief of the Division of Abdominal Transplant (1999 to present) and am well positioned to serve as a co-investigator on the "Organ Donor Anemia Randomized Transfusion Trigger Trial (The DARTT trial)" grant currently under consideration. I have the expertise, leadership, and motivation necessary to successfully participate in the proposed project. As a transplant surgeon at the Transplant Program at the University of California, San Francisco since 1988, I am involved in the pre- and post-operative evaluation and management of our liver and kidney transplant candidates and perform many of our adult and pediatric living donor kidney transplantations.

With a dedicated team of 7 additional transplant surgeons, five adult nephrologists, three pediatric nephrologists, and clinical transplant fellows, the UCSF program has consistently facilitated approximately 200 deceased donor kidney transplants annually and 100-140 living donor kidney transplants annually. The support team consists of nurse coordinators, physician assistants, financial counselors, social workers, and administrative assistants. A long established program, we continue to be a leading center for living donor transplant, both in terms of outcomes and volume, but the volume of necessity must be improved.

B. POSITIONS AND HONORS:

Positions and Employment

1988-1993	University of California, San Francisco, Assistant Professor
1993-1997	University of California, San Francisco, Associate Professor
1997-present	University of California, San Francisco, Professor
1999-present	University of California, San Francisco, Chief, Division of Transplantation
1990-2005	University of California, San Francisco, Program Director, Abdominal Transplant Fellowship Program
1992-2002	California Pacific Medical Center, SF, Surgical Director, Liver Transplantation
1999 – present	UCSF Medical Center, Director, Division of Transplant
1999 – present	UCSF Medical Center, Surgical Director, Liver Transplant Program
2009 – present	Children's Hospital Central California, Madera, CA, Consulting

Honors

1991	Chief Resident Teaching Award, Department of Surgery, UCSF
1992	Chief Resident Teaching Award, Department of Surgery, UCSF
2001	Best Doctors in America (2001-2012), Best Doctors, Aiken, South Carolina
2005	Exceptional Physician Award, UCSF Medical Center
2007	Author of the 40th Anniversary Landmark paper, Winter Simulation Conference 2007
2009	American Liver Foundation (3-14-2009), Honoree, Salute to Excellence.
2011	Top Doctor, in top 1% in nation in transplant specialty, U.S. News and World Report

C. SELECTED PEER-REVIEWED PUBLICATIONS (IN CHRONOLOGICAL ORDER)

(Publications selected from 242 peer-reviewed publications)

1. Stock, PG, Roland, ME, Carlson, L, Freise, CE, Roberts, JP, Hirose, R, Terrault, NA, Frassetto, LA, Palefsky, JM, Tomlanovich, SJ, and Ascher, NL. Kidney and liver transplantation in human immunodeficiency virus-infected patients: a pilot safety and efficacy study. Transplantation, Jul 2003;76(2):370-5.
2. Chang, GJ, Mahanty, HD, Ascher, NL, and Roberts, JP. Expanding the donor pool: can the Spanish model work in the United States? Am J Transplant, Oct 2003;3(10):1259-63.
3. Roberts, JP, Nikolai, B, and Tomlanovich, S. Cost of organ procurement and transplantation network data collection for a large transplant center. Am J Transplant, Oct 2003;3(10):1316-7.
4. Roberts, JP, Wolfe, RA, Bragg-Gresham, JL, Rush, SH, Wynn, JJ, Distant, DA, Ashby, VB, Held, PJ, and Port, FK. Effect of changing the priority for HLA matching on the rates and outcomes of kidney transplantation in minority groups. N Engl J Med, Feb 2004;350(6):545-51.
5. Ponrartana S, Coakley FV, Yeh BM, Breiman RS, Qayyum A, Joe BN, Poder L, Lu Y, Gibbs VC, Roberts JP. Accuracy of plain abdominal radiographs in the detection of retained surgical needles in the peritoneal cavity. Ann Surg 247: 8-12, Jan/2008.
6. Roland ME, Barin B, Carlson L, Frassetto LA, Terrault NA, Hirose R, Freise CE, Benet LZ, Ascher NL, Roberts JP, Murphy B, Keller MJ, Olthoff KM, Blumberg EA, Brayman KL, Bartlett ST, Davis CE, McCune JM, Bredt BM, Stablein DM, Stock PG. HIV-infected liver and kidney transplant recipients: 1- and 3-year outcomes. Am J Transplant 8: 355-65, Feb/2008.
7. Park Y, Hirose R, Dang K, Xu F, Behrends M, Tan V, Roberts JP, Niemann CU. Increased severity of renal ischemia-reperfusion injury with venous clamping compared to arterial clamping in a rat model., Surgery 143: 243-51, Feb/2008.
8. Blasi-Ibanez A, Hirose R, Feiner J, Freise C, Stock PG, Roberts JP, Niemann CU. Predictors associated with terminal renal function in deceased organ donors in the intensive care unit., Anesthesiology 110(2): 333-41. Feb/2009.
9. Freeman RB, Matas AT, Henry M, Segev DL, Kaufman DB, Roberts JP. Moving kidney allocation forward: the ASTS perspective. Am J Transplant, Jul/2009;9(7):1501-6.
10. Tavakol MM, Vincenti FG, Assadi H, Frederick MJ, Tomlanovich SJ, Roberts JP, Posselt AM. Long-term renal function and cardiovascular disease risk in obese kidney donors. Clin J Am Soc Nephrol, Jul/2009;4(7):1230-8.
11. Ahearn AJ, Posselt AM, Kang SM, Roberts JP, Freise CE. Experience with laparoscopic donor nephrectomy among more than 1000 cases. Arch Surg Jul/2011;146:859-864.
12. Segev DL, Veale JL, Berger JC, Hiller JM, Hanto RL, Leeser DB, Geffner SR, Shenoy S, Bry WI, Katznelson S, Melcher ML, Rees MA; Samara EN, Israni AK, Cooper M, Montgomery RJ, Malinzak L, Whiting J, Baran D, Tchervenkov JI, Roberts JP, Rogers J, Axelrod DA, Simpkins CE, Montgomery RA. Transporting live donor kidneys for kidney paired donation: initial national results. Am J Transplant, Feb/2011;11(2):356-60.
13. Ashby VB, Port FK, Wolfe RA, Wynn JJ, Williams WW, Roberts JP, Leichtman AB. Transplanting kidneys without points for HLA-B matching: consequences of the policy change. Am J Transplant, Aug/2011;11(8):1712-18.
14. Mast DA, Vaughan W, Busque S, Veale JL, Roberts JP, Straube BM, Flores N, Canari C, Levy E, Tietjen A, Hil G, Melcher ML. Managing finances of shipping living donor kidneys for donor exchange. Am J Transplant, Sep/2011;11(9):1810-14.

15. Washburn K, Pomfret E, Roberts J. Liver allocation and distribution: possible next steps. Liver Transpl, Sep/2011;17(9):1005-1012.

D. RESEARCH SUPPORT:

Ongoing Research Support

N01 AI15416 ITN Project 0291 Feng (PI) **04/01/06-01/31/15**
NIH – NIAID
Title: Immunosuppression Withdrawal for Stable Pediatric Living Donor Liver Transplant Recipients.
Purpose: The primary clinical endpoints are the efficacy and safety of gradual and complete immunosuppression withdrawal in a select subgroup of liver transplant recipients.
Role: Co-Principal Investigator

N01 AI15416 ITN Project 030ST Feng (PI) **09/30/01-01/31/15**
NIH – NIAID
Title: Immunosuppression Withdrawal in Transplantation".
Purpose: The trial examines the relationship between the clinical outcomes and the immune responses in liver transplant recipients who have liver failure related to hepatitis C infection or nonimmune, nonviral liver diseases and who have been maintained on, or withdrawn from, immunosuppression.
Role: Co-Principal Investigator

U01 DK62500 **Rosenthal (PI)** **9/15/2002 – 5/31/2019**
NIH NIDDK
Childhood Liver Disease Research and Education Network (ChiLDREN)
The major goals of this project are, through a national consortium, to establish a large patient database and to explore a possible etiologic relationship between HLA type and biliary atresia and allow a prospective evaluation of the PELD score.
Role: Co-Investigator

R38OT22183-01-00 **Niemann (PI)** **09/01/11-08/31/15**
HRSA
Title: The effect of therapeutic hypothermia on deceased donor renal graft outcomes – a randomized controlled trial from the Region 5 donor management goals workgroup
Purpose: To demonstrate that 1) therapeutic hypothermia as an active medical intervention for the donation after neurologic determination of death (DNDD) donor; and 2) compliance with donor management goals (DMGs) can substantially improve allograft function and survival.
Role: Co-Principal Investigator

Pilot Research Award **Trompeta (PI)** **01/01/12-12/31/14**
REAC Pilot
Title: Factors Limiting the Number of Live Kidney Donations
Purpose: The proposed retrospective study of UCSF's kidney transplant database and charts for the past 10 years seeks to accomplish three aims: (1) determine and quantify the medical and non-medical reasons that ruled-out potential living kidney donors; (2) identify when in the donor evaluation process potential kidney donors were found to be unsuitable to donate, and determine whether they were referred to an alternative living donation program; and (3) determine whether the choice not to donate due to cultural or medical concerns differs depending on race/ethnicity.
Role: Co-PI

Completed Research:

5501-G000-202 - **Terrault (PI)** **02/24/2010 - 12/31/2011.**
Eisai Global Clinical Development

Title: A Phase 2, Randomized, Multicenter, Placebo-Controlled, Double-Blind, Parallel-Group Study to Evaluate the Efficacy, Safety, and Population Pharmacokinetics of Once-Daily Oral E5501 Tablets Used Up to 7 Days in Subjects with Chronic Liver Diseases and Thrombocytopenia Prior to Elective Surgical or Diagnostic Procedures".
Purpose: This is a Phase 2, randomized, multicenter, placebo-controlled, double-blind, parallel-group study to evaluate the efficacy, safety, and population pharmacokinetics of once-daily oral E5501 tablets used up to 7 days in subjects with chronic liver diseases and thrombocytopenia prior to elective surgical or diagnostic procedures.
Role: Co-Principal Investigator

COLO400A2426 **Roberts (PI)** **09/14/2005 - 12/31/2010**
Novartis Pharmaceuticals - Industry Sponsored Trial
Title: A multi-center, randomized, open-label study to compare the development of liver fibrosis at 12 months after transplantation for hepatitis C cirrhosis in patients receiving either Neoral or tacrolimus.
Purpose: This is a multi-center, randomized study to compare the development of liver fibrosis at 12 months after transplantation for hepatitis C cirrhosis in patients receiving either Neoral or tacrolimus
Role: Principal Investigator

ADS-TCAD-P0206 **Roberts (PI)** **10/31/2009 - 11/01/2010**
Adamas Pharmaceuticals - Industry Sponsored Trial
Title: A Randomized Open Label Study Comparing the Efficacy, Safety, and Tolerability of Oral Administration of Amantadine and Ribavirin with Oseltamivir Versus Oseltamivir to Influenza A Virus Infected Immunocompromised Subjects.
Purpose: The purpose of the study was to investigate the virologic benefit, clinical efficacy, safety, and tolerability of amantadine and ribavirin with oseltamivir (TCAD) versus oseltamivir monotherapy for the treatment of all strains of influenza A in immunocompromised subjects.
Role: Principal Investigator

R21 DK078702-01A2 **Posselt (PI)** **09/21/09-06/30/12**
NIH - NIH
Title: Effect of Obesity on Long-term Clinical Outcomes after Kidney Transplant.
Purpose: This study examines the impact of obesity on long-term renal function and development of hypertension and other risk factors for cardiovascular disease in patients who donated a kidney at UCSF.
Role: Co-Principal Investigator

AEB071 B2201 **Roberts (PI)** **03/22/10-12/31/12**
Novartis Pharmaceuticals - Industry Sponsored Trial
Title: A 24-month randomized, multicenter study, evaluating efficacy, safety, tolerability and pharmacokinetics of sotrastaurin (STN) combined with tacrolimus (TAC) vs. a tacrolimus/mycophenolate mofetil (MMF)based control regimen in de *novo* liver transplant recipients".
Purpose: The purpose of this study is to evaluate the efficacy and safety of sotrastaurin (STN) + tacrolimus (Tac) in liver transplantation and to provide further information to optimize the dosing combination of these study drugs.
Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Vartanian, Shant M.	Assistant Professor In Residence
eRA COMMONS USER NAME (credential, e.g., agency login) VARTANIAN	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Stanford University	BS	1998	Biology
Saint Louis University	MD	2003	Medicine
University of California, San Francisco	Residency	2003-2010	General Surgery
University of California, San Francisco	Research Fellowship	2005-2007	Vascular Biology
University of California, San Francisco	Clinical Fellowship	2010-2012	Vascular Surgery

A. Personal Statement

Dr. Vartanian graduated from Stanford University with a Bachelors degree in Biology and then went on to Saint Louis University for his medical education. He finished his general surgery residency at the University of California, San Francisco (UCSF) in 2010. During his residency, he spent two years working in the Laboratory for Accelerated Vascular Research (LAVR) under the direction of Rong Wang, Ph.D. His research focused on notch signaling and how that plays a critical role in vascular morphology during embryonic vascular development. Dr. Vartanian completed the fellowship in Vascular and Endovascular Surgery and is now on faculty at UCSF. Dr. Vartanian is interested in comparing the effectiveness of endovascular treatments for peripheral arterial disease. By understanding the safety, effectiveness, and cost of each intervention, the aim of the research is to assist patients and clinicians in making informed decisions about treatment options.

B. Positions and Honors

Principals Positions Held

2012- Assistant Professor of Surgery, Division of Vascular and Endovascular Surgery, UC San Francisco

Honors and Awards

1994	Departmental Honors (Biology)	Stanford University
2007	Outstanding Presentation, J. Engelbert Dunphy Annual Resident Research Symposium	University of California, San Francisco
2010	Fred H. and Esther E. Nusz Achievement Award	University of California, San Francisco

Memberships

2011 - present	Society of Vascular Surgery, Candidate Member
2013 - present	American Heart Association, Professional Member
2003 - present	American College of Surgeons, Resident Member
2005 - 2010	North American Vascular Biology Organization
2010 - present	Naffziger Surgical Society, Member
2012 - present	Northern California Vascular Society

C. Selected Peer-Reviewed Publications

1. Scharff JR, Longo WE, Vartanian SM, Jacobs DL, Bahadursingh AN, Kaminski DL. *Ischemic colitis: spectrum of disease and outcome. Surgery.* 2003 Oct;134(4):624-9.

2. Vartanian SM, Colaco S, Orloff LE, Theodore PR. Oklahoma prosthesis: resection of tumor of clavicle and chest wall reconstructed with a custom composite graft. *Ann Thorac Surg.* 2006 Jul;82(1):332-4.

3. Murphy PA, Lam MT, Wu X, Kim TN, Vartanian SM, Bollen AW, Carlson TR, Wang RA. Endothelial Notch4 signaling induces hallmarks of brain arteriovenous malformations in mice. *Proc Natl Acad Sci U S A.* 2008 Aug 5;105(31):10901-6.

4. Johnston PC, Vartanian SM, Runge SJ, Hiramoto JS, Eichler CM, Owens CD, Schneider DB, Conte MS. Risk factors for clinical failure following stent-graft treatment for femeropopliteal occlusive disease. J Vasc Surg. 2012 Oct;56(4):998-1006

5. Vartanian SM, Johnston PC, Walker JP, Runge SJ, Eichler CM, Reilly LM, Hiramoto JS, Conte MS. Clinical consequence of bare metal stent and stent graft failure in femoropopliteal occlusive disease. J Vasc Surg. 2013 Jul 30.

D. Research Support

<u>On-going Research Support</u>

None

<u>Completed Research Support</u>

None

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Wieselthaler, Georg	Professor of Surgery Director & Surgical Chief, Cardiac Transplantation and Mechanical Circulatory Support
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
College for Electrical Engineering, Vienna, Austria	BS	1978	Electrical Engineering
Medical University of Vienna, Vienna, Austria	MD	1987	Medicine
Military Hospital, Vienna, Austria		1988-89	Surgery
Medical University of Vienna, Vienna, Austria		1989-95	Surgery Residency

A. Personal Statement

I am one of the world's leading experts in the use of different forms of mechanical circulatory support in end stage heart failure patients. Over the past 20 years, I have performed more than 400 heart transplants. I have extensive experience with numerous ventricular assist device (VAD) systems implanted at the Medical University of Vienna. This institution has been developing and applying pulsatile ventricular assist devices (VADs) and a total artificial heart ("The New Vienna Total Artificial Heart") since the early 1970s. In 1984, while still in Medical School at the University of Vienna after graduating as an electrical engineer, I became involved in the VAD program at the 2nd Department of Surgery at the University of Vienna (chair: Prof. E. Wolner). I started working in the Biomedical Laboratory (chair: Prof. H. Thoma) on the development of the driving unit for the "New Vienna TAH". In the late 1980s, after graduating from medical school, I became aware of the advantages of rotary blood pumps and organized the world´s first International Workshops on Rotary Blood Pumps in 1988 and 1991 in Austria. Out of these meetings the International Society for Rotary Blood Pumps was founded in 1992 and I acted for many years as the Secretary General. Together with my colleague Dr. Heinrich Schima, a biomedical engineer, we have been developing and investigating miniaturized centrifugal pumps for more than 15 years in the Biomedical Laboratories of the University of Vienna. I then became the primary surgeon implanting the various VAD systems and was supervising patient care at the Medical University of Vienna. I have extensive experience with pulsatile systems, such as the Novacor LVAS, with one of the longest supported patients of more than four and a half years, as well as the Thoratec paracorporeal and implantable VADs and participated in the Arrow LionHeart CUPS Trial, with a patient supported more than 3 years on this world´s first full implantable VAD. In 1998 I implanted the world's first implantable, miniaturized axial flow pumps, the MicroMed-DeBakey VAD, and I have since then supported more than 80 patients with this pump. Out of this early experience with the world´s first nonpulsatile pump, many of my high ranking scientific papers originate, and are currently cited within the VAD community. I also acted as the Principal Investigator in my center and implanted the world´s first implantable, magnetically suspended centrifugal LVAD, the TERUMO DuraHeart LVAD. In 2003 I joined as a consultant to a start-up company (HeartWare Inc, Miramar, FL), and within the next three years the HeartWare HVAD, a miniaturized hydromagnetically levitated centrifugal pump, was developed. In March 2006 the world´s first patients with this system were implanted in Vienna. I continued working with HeartWare, Inc. on the next generation LVAD, the MVAD, and out of this work two patents were filed under my name (a minimal invasive implantation technique of the MVAD, and a special shaped inflow cannula tip for the MVAD).

I have trained colleagues from all parts of the world in the implantation technique, and use of different pulsatile and continuous flow ventricular assist devices in his institution, and I am proctoring implants throughout Europe and Asia Minor. I am a member of several national and international medical scientific societies, immediate past President of the International Society for Rotary Blood Pumps, Director of the European Society for Artificial Organs, and Past President of the Austrian Society for Implantology and Tissue Integrated Prosthetics. In addition, I have acted as Director of the International Society for Heart and Lung Transplantation from April 2011 to 2014. Within the last ten years I have been invited as speaker and chair to many national and international scientific conferences in the field of mechanical circulatory support and transplantation. In November of 2011, I joined the University of California San Francisco as the Director and Surgical Chief of Cardiac Transplantation and Mechanical Circulatory Support. Since then, I have been

continuing my clinical and research interests in cardiac implantation devices.

B. Positions and Honors

Positions and Employment

1995-1999	Staff Surgeon, Vienna General Hospital, Medical University of Vienna
1996-1998	Advance Fellowship, Staff Surgeon at the Dept. of Cardiac Surgery, St. Pölten Hospital, Austria
1998-2000	Fellow, Vienna Heart Transplant Program (Program Director: Univ. Prof. Dr. G. Laufer)
1999-2011	Senior Staff Surgeon, Vienna General Hospital, Medical University of Vienna
1999-2011	Medical Director, Mechanical Circulatory Support Program, Medical University of Vienna
2000-2003	Assistant Professor of Surgery, Medical University of Vienna
2000-2003	Fellow, Vienna Lung Transplant Program (Program Director: Univ. Prof. Dr. W. Klepetko)
2000-2011	Vice Director, Clinical Heart Transplant Program, Medical University of Vienna
2003-2011	Associate Professor of Cardiothoracic Surgery, Medical University of Vienna
2005-2011	Director, Interdisciplinary Surgical Heart Failure Program, Medical University of Vienna
2011-2014	Director, International Society for Heart and Lung Transplantation
2011-	Professor of Surgery, University of California, San Francisco (UCSF)
2011-	Director and Surgical Chief, Cardiac Transplantation and Mechanical Circulatory Support, UCSF

Honors and Awards

1999	Visiting Fellow, Baylor College of Medicine, Houston, TX
1999	Medforte-Olsen Clinical Award, The International Society for Rotary Blood Pumps
2001	Medforte-Olsen Clinical Award, The International Society for Rotary Blood Pumps
2002	Stefan Schuy-Award, The Austrian Society for Biomedical Engineering

C. Selected Peer-Reviewed Publications

Most relevant to the current application

1. Wieselthaler GM, Schima H, Hiesmayr M, Pacher R, Laufer G, Noon GP, DeBakey M, Wolner E. First clinical experience with the DeBakey VAD continuous-axial-flow pump for bridge to transplantation. Circulation. 2000 Feb 1;101(4):356-9.
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3. Wieselthaler GM, Schima H, Wolner E. Special considerations on the implantation technique for the MicroMed-DeBakey ventricular assist device axial pump. Ann Thorac Surg. 2003 Dec;76(6):2109-11.
4. Wieselthaler GM, Riedl M, Schima H, Wagner O, Waldhäusl W, Wolner E, Luger A, Clodi M. Endocrine function is not impaired in patients with a continuous MicroMed-DeBakey_axial flow pump. J Thorac Cardiovasc Surg. 2007 Jan;133(1):2-6.
5. Wieselthaler GM, O Driscoll G, Jansz P, Khaghani A, Strueber M; HVAD Clinical Investigators. Initial clinical experience with a novel left ventricular assist device with a magnetically levitated rotor in a multi-institutional trial. J Heart Lung Transplant. 2010 Nov(11):1218-25

Additional recent publications

1. Alexander Eskandary F, Kohl M, Dunkler D, Aliabadi A, Grömmer M, Schiferer A, Gökler J, Wieselthaler G, Laufer G, Zuckermann A. Lack of donor and recipient age interaction in cardiac transplantation. J Heart Lung Transplant. 2014 Jun; 33(6):629-35.
2. Strueber M, Larbalestier R, Jansz P, Zimpfer D, Fiane AE, Tsui S, Simon A, Schmitto JD, Khaghani A,Wieselthaler GM, Najarian K, Schueler S. Results of the post-market Registry to Evaluate the

HeartWare Left Ventricular Assist System (ReVOLVE). J Heart Lung Transplant. 2014 May; 33(5):486-91.
3. Schima H, Zrunek P, Stoiber M, Larose J, Shambaugh C, Tamez D, Deckert Z, Plasenzotti R, Bergmeister H,Wieselthaler G. Extended in vivo evaluation of a miniaturized axial flow pump with a novel inflow cannula for a minimal invasive implantation procedure. J Heart Lung Transplant. 2014 Apr; 33(4):422-8.
4. Sandner SE, Riebandt J, Haberl T, Mahr S, Rajek A, Schima H, Wieselthaler GM, Laufer G, Zimpfer D. Low-molecular-weight heparin for anti-coagulation after left ventricular assist device implantation. J Heart Lung Transplant. 2014 Jan; 33(1):88-93.
5. Plass CA, Wieselthaler GM, Podesser BK, Prusa AM. Low-level-laser irradiation induces photorelaxation in coronary arteries and overcomes vasospasm of internal thoracic arteries. Lasers Surg Med. 2012 Nov; 44(9):705-11.
6. Granegger M, Moscato F, Casas F, Wieselthaler G, Schima H. Development of a pump flow estimator for rotary blood pumps to enhance monitoring of ventricular function. Artif Organs. 2012 Aug; 36(8):691-9.
7. Westaby S, Anastasiadis K, Wieselthaler GM. Cardiogenic shock in ACS. Part 2: Role of mechanical circulatory support. Nat Rev Cardiol. 2012 Apr; 9(4):195-208.
8. Moscato F, Granegger M, Naiyanetr P, Wieselthaler G, Schima H. Evaluation of left ventricular relaxation in rotary blood pump recipients using the pump flow waveform: a simulation study. Artif Organs. 2012 May; 36(5):470-8.
9. Geidl L, Deckert Z, Zrunek P, Gottardi R, Sterz F, Wieselthaler G, Schima H. Intuitive use and usability of ventricular assist device peripheral components in simulated emergency conditions. Artif Organs. 2011 Aug; 35(8):773-80.
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D. Research Support

Ongoing Research Support

Austrian National Bank Fund
"Molecular-biological changes in patients with terminal heart failure under left ventricular assist device support"
Ongoing research project at the Medical University of Vienna, Austria

Completed Research Support

1985-1988: Investigation on production and influence of a novel atrial natriuretic factor (ANP) in an experimental setting with central venous congestion and low cardiac output and in a clinical TAH setting

1989 – 1991: Development of a clinical applicable device for tissue impedance measurement for rejection monitoring after cardiac transplantation

1992 – 1995: Development of an implantable seal-less centrifugal pump with integrated double-disk motor

1995 - 1998: Principal Investigator of a randomized, prospective Phase III-Study for FDA approval: "Celsior - a new preservation solution in clinical heart transplantation"

1998 – 2001: Principal Investigator: "First clinical use of the miniaturized, implantable MicroMed-DeBakey axial flow pump"

1999 – 2002: Principal Investigator of the ARROW LionHeart 2000 trial; first full implantable left ventricular assist pump with transcutaneous energy transmission for destination therapy

2003 – 2005: Principal Investigator of the TERUMO DuraHeart trial; first clinical application of a magnetically levitated centrifugal pump

2006 – 2009: Principal Investigator of the HeartWare HVAD trial; first clinical application of a new, miniaturized, magnetically levitated centrifugal pump

2008 – 2011: Minimal invasive implantable HeartWare MVAD, feasibility studies and initial animal experiments with continued long-term studies

2007 – 2011: Research in apoptosis in idiopathic dilated cardiomyopathy: Collaboration with the molecular-biology laboratory Prof. Dr. S. Aharinejad

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? ○ Yes ● No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ○ Yes ○ No

IRB Approval Date:

Human Subject Assurance Number

2. * Are Vertebrate Animals Used? ● Yes ○ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ● No

IACUC Approval Date: 03-05-2015

Animal Welfare Assurance Number A3400-01

3. * Is proprietary/privileged information included in the application? ○ Yes ● No

4.a. * Does this project have an actual or potential impact on the environment? ○ Yes ● No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place? ○ Yes ● No

4.b. If yes, please explain:

6. * Does this project involve activities outside the United States or partnership with international collaborators? ○ Yes ● No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract	ROY_Summary.pdf	Mime Type: 23921_12158
8. * Project Narrative	ROY_Narrative.pdf	Mime Type: 23922_12158
9. Bibliography & References Cited	REFERENCES.pdf	Mime Type: 25828_12158
10. Facilities & Other Resources	Facilities_Resources.pdf	Mime Type: 23854_12158
11. Equipment		
12. Other Attachments	Candidate_Eligibility.pdf	Mime Type: 23911_12158
12. Other Attachments	MosesWillie_transcript.pdf	Mime Type: 23933_12158

PROJECT SUMMARY/ABSTRACT

Treatment of end stage renal disease (ESRD) patients by renal transplant is severely limited by shortage of donor organs, while dialysis is expensive, inconvenient, and confers significant morbidity and mortality. There are nearly 400,000 people in the US who rely on thrice-weekly, in-center hemodialysis, and collectively, this population consumes over $20 billion annually in Medicare-paid healthcare. The prevalence of ESRD is increasing at 5% per year, and the vast majority of patients are unlikely to ever receive a transplant. Consequently, our long term goal is to develop an implantable renal replacement device that combines a silicon hemofilter with a bioreactor of human renal tubule cells to mimic nephronal function. In this device, blood will first be filtered, under the driving force of the arterial-venous pressure difference, through silicon nanopore membranes (SNM) to remove uremic toxins, salts, small solutes, and water. Then, the resulting ultrafiltrate will be processed by the cells in the bioreactor to selectively transport most of the salts and water back into the blood, thereby maintaining volume homeostasis and electrolyte balance.

Our team has achieved promising progress towards the development of a “no-additional-pump required” or a, “pump-less” SNM hemofilter for the implantable bioartificial kidney. A key criterion for long-term functional performance of the implanted silicon hemofilter will be its blood compatibility with respect to clot formation (thrombosis) and plasma protein adsorption (membrane fouling). The proposed R01 project will attempt to better understand the blood-device interactions that could limit future clinical utility of the SNM hemofilter. More specifically, we will evaluate the impact of membrane physicochemical properties on mass transfer characteristics and determine the role of fluid flow anomalies in device thrombosis. The work will establish a new *in vivo* testing methodology for implantable devices that are functionally dependent on features at both large (mm-cm) and small (nm-microns) length scales.

PROJECT NARRATIVE

We are working to develop an implantable bioartificial kidney for patients who are dialysis. Our device combines a nanoscale filter with a bioreactor of cells to provide many of the functions of a healthy kidney.

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FACILITIES AND RESOURCES

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

The University of California, San Francisco (UCSF) is comprised of the Schools of Medicine, Nursing, Dentistry, and Pharmacy. One of the top medical schools in the country, UCSF's School of Medicine ranked 1st in National Institutes of Health (NIH) funding in 2012. The 107-acre Parnassus campus is home to graduate professionals in dentistry, medicine, nursing, and pharmacy; a graduate division for predoctoral and postdoctoral scientists; UCSF Medical Center; UCSF Children's Hospital; and Langley Porter Psychiatric Institute. UCSF also includes the UCSF Mt. Zion campus and its newest campus, a 43-acre research center at Mission Bay in San Francisco, adding 732,000 square feet of laboratory research space. By 2015, the Mission Bay campus will also be home to a 289-bed, 878,000 square foot hospital complex dedicated to women, children, and cancer patients. Over 1,700 strong, the UCSF faculty currently includes five Nobel laureates, 42 National Academy of Sciences members, 61 American Academy of Arts and Sciences members, 89 Institute of Medicine members, and 18 Investigators of the Howard Hughes Medical Institute.

The campus has excellent **central computing facilities**. All of the investigators' laboratories contain personal computers as well as computers dedicated to imaging and microscopy. In addition, both they and their assistants have access to networked computers and to supporting technical help. All computers are equipped with basic desktop software such as the Microsoft Office Suite and Adobe Acrobat Pro, and those dedicated to imaging and microscopy have appropriate software suites for operation of equipment and data acquisition.

Dr. Roy has an **office** on the second floor of the QB3 building at the UCSF Mission Bay Campus. He and his team are within the same QB3 building as their laboratories. Dr. Roy has access to several conference rooms equipped with state-of-the-art audiovisual equipment and teleconferencing capability. There is desk space in the adjacent laboratories and common office area for graduate student researchers, postdoctoral research fellows, and other laboratory researchers.

The UCSF Library and Center for Knowledge Management is designed to advance science, foster excellence in teaching and learning, and promote health through the collection, development, organization, and dissemination of the world's health sciences knowledge base. One of the preeminent health sciences libraries in the world, the UCSF Library serves not only as a repository for health sciences information, but also as a center for development of electronic information resources and the hub of instructional computing on the UCSF campus. The Library acquires and maintains a collection of materials necessary to support the research, patient care, education, and community service programs at UCSF. With over 830,000 volumes and more than 900 journals in print formats, the Library's collection covers the spectrum of the health sciences disciplines. GALEN, the digital library of UCSF, provides the campus community with integrated access to health sciences information and Library services. The website provides access to more than 100 selected databases and over 15,000 online journals in a wide variety of subject areas.

In sum, there are over 1,000 research laboratories and 2,200 active research projects at UCSF. In addition to the basic support services (library services, biostatistical cores, computing infrastructure, office of research administration, and animal facilities) and extensive collaborative opportunities inherent to a research enterprise of this size, we will rely on the following resources to complete the work outlined in this proposal:

BIODESIGN LABORATORY

The Biodesign Laboratory, located in QB3 at the University of California, San Francisco (UCSF) Mission Bay campus is a state-of-the-art facility managed by Dr. Shuvo Roy and optimized for bioMEMS research and development. This laboratory is equipped with extensive software and hardware tools for the design, packaging and characterization of biomedical microsystems. Software available for MEMS design and modeling include:

- L-Edit for mask layout
- S-Edit and T-Spice for schematic design and electrical simulation

- SONNET for RF design and analysis
- ANSYS and COMSOL for finite-element modeling and computational fluid dynamics.

To accommodate the unique testing requirements of MEMS devices, a specially instrumented Karl Suss PM-5 probe station is available for micro-sensor testing, calibration, and micro-actuator characterization. A high resolution optical inspection system consisting of a long working distance Mitutoyo microscope, an Optronics megapixel CCD camera, and a digital video display system is connected to the probe station to enable viewing and recording. Associated electronic instrumentation include:

- Kronhite wideband power amplifier
- Tektronix TD20A and HP 54600B oscilloscopes
- Keithley 2000 multimeters
- HP 33120A frequency generators
- HP 5314A universal counter
- HP 6205C high voltage dual power supply
- 6209B HP high voltage single power supply
- HP E3614A dc power supplies
- Keithley LCZ meter

Also available are a high frequency strobe light, HP 4395A and 4395B network analyzers, and a HP 87511 s-parameter test set. These tools allow for the investigation and analysis of dynamic characteristics at the microscale. Additionally, the laboratory is equipped with an apparatus to measure mechanical properties of thin film MEMS materials. The system consists of a Leitz interferometer, a custom-built regulated pressure manifold, and a LabView-based data acquisition system.

The following equipment is frequently used for work on **The Kidney Project**, our pioneering project to develop an implantable, bioartificial kidney that will mimic many of the biological and metabolic functions of a natural kidney. Much of the work done on The Kidney Project will directly inform our work on the artificial pancreas, and the following testing facilities will be utilized:

Mechanical Properties Testing Station: Mechanical properties of thin film MEMS materials can be determined using this customized apparatus, which consists of a reflection-type optical microscope mounted with a Mirau interferometer attachment, a custom-built regulated pressure manifold, and LabVIEW-based data acquisition system. Load-deflection testing can be performed to extract Young's modulus, residual stress, as well as burst pressure tests up to 250 psi.

Fluid Flow Testing Station: This automated flow diagnostics system is available to test micro/nanofluidic devices. Flow rates can be measured by monitoring volume displacement in a calibrated microsyringe barrel (Figure B). In an alternate mode, gravimetric flow rate measurement is possible using a precision balance capable of microgram resolution. The system incorporates a custom flow and purging system to minimize bubbles and contaminants in the FEED or PERMEATE chambers. The system has been used to accurately and reproducibly measure flow rates as low as 0.3 μl/min. The system is controlled by a custom software and data acquisition system.

Membrane Inspection and Repair Station (Figure 1): Silicon chips can be scanned for membrane fractures and repaired using a computer-controlled semi-automated apparatus, which consists of a transmission optical microscope, 3-axis motion stage and controller, a piezo-driven epoxy dispenser. In typical operation, the membrane is mounted with cavity-side facing upwards so that light can

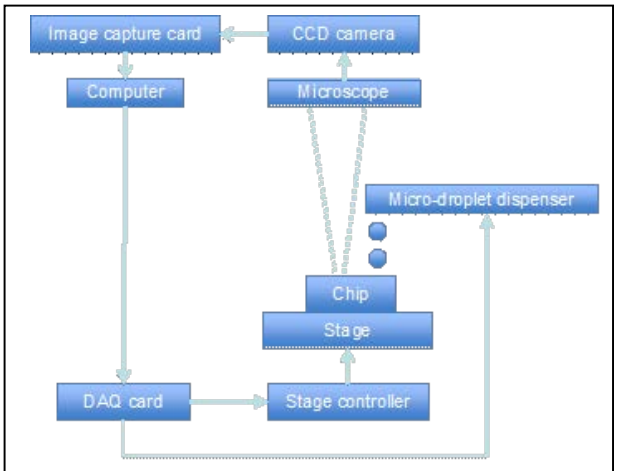

Figure 1: Schematic concept of semi-automated membrane inspection and repair system. The membrane chip rests on a microscope stage that is controlled automatically via a computer interface and stage controller. An image-capture card and pattern recognition software is used to determine damaged membranes. Epoxy is dispensed by a piezo-driven micro-droplet dispenser to seal cavities of the defective membranes.

shine through the membrane. As the stage is scanned at constant speed (1 mm-5mm per second), light from broken membranes (brighter) is detected, and the stage stopped. The epoxy dispenser is used to deposit a microdroplet of glue into the membrane cavity, and then, stage is set into motion again. This procedure is repeated until all fractured membranes are epoxied, and then the membrane chip is put into a ultra-violet (UV) cure chamber to harden the epoxy and seal membranes water-tight.

BIOMEDICAL MICRO/NANO FABRICATION CORE FACILITY

The Biomedical Micro/Nano Fabrication Core Facility is a shared Class 10000 cleanroom housed on the first and second floors of Genentech and Byers Halls and open to all researchers at the University of California, San Francisco (UCSF) and the California Institute for Quantitative Biosciences (QB3). It houses tools that allow researchers to fabricate and characterize biomedical micro- and nano-systems including surface modification, mold masters, rapid prototyping, polymer processing and mold formation, all within the 500 square-foot space. It has opened the door for new and novel research, ranging from the use of cutting-edge tools for studying cellular phenomenon to new materials for implantable devices, that advances work in the growing areas of drug delivery, regenerative medicine, and point-of-care diagnostics. Specific areas that have been enabled by this resource include microfluidic cell-based assays, nanoscale probes for imaging, biomaterials for orthopedic applications, and drug delivery platforms for tumor targeting.

This facility contains specialized equipment including YES-58TA vapor prime oven, Blue M DCI-146-B-MP550 convection oven, Binder vacuum oven, Karl Suss RC8 MS3 spin coater, full programmable digital hot plates, sensors, Oriel 87436-1000 UV exposure source, Metroline M4L asher system, Disco DAD 320 saw, a multi-mode inspection microscope, two wet processing stations, and a spin-rinse-dryer. It also includes a Headway Research PWM32-PS-R790 spin coater, Karl Suss MJB3 mask aligner, PDMS hole punch for microfluidics preparation of PDMS devices, WAFAB wet process stations and Ambios XP-2 profilometer. Cleanroom space has additionally been allocated for a dip coater, maskless lithography, metal deposition, and RIE etcher.

The facility has trained 60 users from 12 different UCSF labs since its establishment and currently has over 30 active, trained users. It has made possible more than twenty publications in scientific journals. The space allows researchers the freedom to design, fabricate, and test micro and nanoscale platforms in close proximity to the many other available resources at USCF, both scientifically and clinically, and without having to divert resources to the use of outside facilities. The first of its kind at UCSF, the Biomedical Mico/Nanofabrication Core Facility has significant implications for the potential of UCSF to be a leader in the development of biomedical research and translational medical technology worldwide.

LABORATORY ANIMAL RESOURCE CENTER

Research will be conducted at the University of California, San Francisco (UCSF) **Laboratory Animal Resource Center (LARC)**. LARC's mission is to provide quality care for all animals used at UCSF, assist the faculty in their mission of quality research with respect to the use of laboratory animals, act as a resource center for the faculty on all issues relating to laboratory animals, and assist the University to meet its goal of humane treatment of laboratory animals. The LARC is administratively part of the Office of Research Services in the Research unit of the university, which has on file with the Office of Protection from Research Risks, National Institutes of Health, U.S. Public Health Service (PHS), an approved Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions (#3400-01). That document expresses UCSF's commitment to comply with PHS policy and all applicable laws and regulations regarding the care and use of laboratory animals in research and instruction. UCSF is accredited by the American Association for Accreditation of Laboratory Animal Care, and LARC is maintained and operated in compliance with the Guide for the Care and Use of Laboratory Animals.

In addition, in compliance with the 1986 NIH upgraded requirements for all research facilities involved in survival procedures utilizing laboratory animals, the facility is directed, supervised and staffed by trained and experienced personnel. The UCSF LARC Survival Surgery Units also provide trained personnel, equipment and facilities for routine management of general anesthesia utilizing state of the art equipment. Staff is

available to provide and ensure that adequate pre- and post-surgical care is provided to experimental animals. The Surgical Research Facility staff have the necessary expertise to provide assure that all procedures requiring the delivery of anesthesia are conducted in compliance with approved animal use and care protocols thus assuring compliance with NIH, AAALAC, and USDA guidelines.

Any research or instructional use of laboratory animals conducted under the jurisdiction of this campus must be reviewed and approved by our Committee on Animal Research (IACUC), the membership and procedures of which fully comply with PHS policy.

THERAPUETIC MICRO AND NANOTECHNOLOGY LABORATORY

Therapeutic Micro and Nanotechnology Laboratory is located in QB3 on the Mission Bay UCSF campus and is under the direction of Dr. Tejal Desai. It contains an in-house micro and nanofabrication facility, atomic force microscope with nanoindentation capability, ellipsometer, goniometer, analytical balance, biohood and fume hood, microscopes, centrifuges, shaker bath, incubators, a cell culture facility and a general biochemistry lab.

The laboratory has access to a wide variety of analytical instrumentation that permits thorough characterization of both small and large molecule drugs. This includes access to multiple high performance liquid chromatography (LCMS) instruments used for either protein or small molecule separation and equipped with UV/Vis multiwavelength detection. They also have access to the **UCSF Mass Spectrometry Facility**, which houses state-of-the-art instrumentation capable of both small and large molecule mass spectrometric analyses, including quantitative and tandem mass spectrometry. For further protein structural characterization, they have access to a spectropolarimeter, a fluorimeter, and dynamic and static light scattering instrumentation. Moreover, they house a shelf-lyophilizer, a UV/Vis spectrophotometer and a fluorimeter in lab and have access to several NMR spectrophotometers through the UCSF NMR facility for high-resolution structural characterization.

In addition, the team has access to: a Varian Cary 300 spectrophotometer, ultracentrifuge with fixed angle and swinging bucket rotors, refrigerated centrifuge with fixed-angle rotor, gamma-scintillation counter; luminescence spectrometer, Millipore Milli-RO and Milli-Q water purification systems, -80o C freezer, Perkin Elmer 9700 PCR machine, Bio-Rad gel-documentation system; Packard phosphorimaging system, and Kodak fluoro-imaging system.

INTERVENTIONAL MRI FACILITY

The UCSF Interventional MRI Facility, in which Dr. Mark Wilson holds a faculty position specializing in body applications, combines 1.5T MRI and X-ray angiography units into one laboratory (Philips Medical Systems: Intera 1.5T MRI, Integris V5000 angiography system), joined with a sliding X-ray / MR-shielded door. All units are O.R. compatible and have support for patient and animal studies with anesthesia. Dedicated laboratory space for laser lithography and manufacture of catheter tip coils is available at the UCSF China Basin research facility (see below). Also located at the China Basin facility is a clinical GE 3.0T MRI unit that can be used for phantom and large animal experiments, as well as a 7.0T small bore experimental MRI unit which can be used for phantom studies. Three blocks from the China Basin facility is the Mission Bay facility, where at 7.0T human-sized experimental MRI unit is available for large animal experiments. C-arm X-ray fluoroscopy units are available at the China Basin and Mission Bay facilities.

THE TRANSPLANT RESEARCH LABORTORY

The Transplant Research Laboratory occupies 4000 sq. ft. on the 5th floor of Health Sciences East tower of the UCSF Parnassus Heights campus, adjacent to the teaching hospital, and is under the direction of Dr. Qizhi Tang. She shares the space with 6 other principal investigators in the transplant division of the Department of

Surgery at UCSF. The common shared facilities include benches, 4 tissue culture rooms, a microsurgery suite, a dark room, an equipment space, and a conference room.

Equipment located in the Transplantation Research Laboratory includes the following: two dissecting microscopes, three biosafety level II laminar flow hoods, two refrigerated tabletop centrifuges, two CO_2 incubators, a large walk-in cold room for media and reagent storage, refrigerators, two -20^{o}C freezers, three -80^{o}C freezers, two liquid nitrogen storage tanks, a step-down freezer for cell cryopreservation, an Accuri flow cytometer for cell counting and 4-color cytometric analysis. The following equipment is freely available in the vicinity: an environmentally controlled fluorescent microscope equipped with CCD camera and time-lapse control for real-time imaging of cultured islets; Bio-Rad iCycler quantitative PCR machine; Fluidigm Biomark quantitative PCR machine; NanoDrop UV-visible spectrophotometer; and Agilent BioAnalyzer.

A Xenogen IVIS Lumina for in vivo bioluminescene imaging is located in the animal facility and is available on a recharge basis.

UCSF/MOFFITT GENERAL CLINICAL RESEARCH CENTER (GCRC) CORE LABORATORY

The mission of the **UCSF/Moffitt GCRC Core Laboratory** is to manage the flow and disposition of biological specimens collected for GCRC studies; coordinate sample distribution, storage and performance of specialized core assays; and to provide facilities and expert personnel for exercise training and testing and for acquisition of body composition data.

The GCRC Core laboratory comprises five main components:

- UCSF Core Genome Analysis Laboratory in collaboration with the UCSF Genomics Core Facility and the UCSF DNA Bank
- GCRC Core Sample Processing Laboratory
- GCRC Core Assay Laboratory
- GCRC Core HPV Laboratory
- GCRC Core Exercise Physiology and Body Composition Laboratory

Specifically, the center has established formal agreements to work with the UCSF Comprehensive Cancer Center Genome Analysis Core Facility to provide a variety of state of the art facilities to GCRC investigators including custom chip synthesis, microarray analyses, Taqman real-time PCR and comparative genomic hybridization. Similarly, they have established a collaboration with the UCSF Genomics Core Facility (GCF). Working with the GCF allows access to high-throughput genotyping.

ADDITIONAL UCSF FACILITIES

Researchers at UCSF -QB3 also have access to several core facilities: **The Membrane Protein Expression Center (MPEC)** develops and applies the latest innovative methods that yield structurally and functionally intact membrane proteins for subsequent drug development, structural, and functional characterization. **The Nuclear Magnetic Resonance Laboratory** includes 600 MHz and 500 MHz spectrometers for high-resolution studies of macromolecules including the solution structure of proteins, nucleic acids, and their complexes. **The Bay Area Screening Center** provides biomedical researchers with improved access to the knowledge, equipment, and reagents needed to carry out high-throughput screening techniques, without heavy investment in infrastructure or purchase of expensiive libraries**.** In addition to those, we frequently use and collaborate with the following research centers.

The Biomechanical Testing Facility (BTF), located at the Orthopaedic Trauma Institute at San Francisco General Hospital specializes in mechanical and cadaver testing of medical devices. The BTF is capable of human and animal cadaver testing, multi-axial testing, failure analysis, internal stress analysis, three-dimensional motion tracking, and medical Imaging. Lab contains all necessary equipment including Philips BV Pulsera 3-D C-arm machine; 2 MTS Bionix Axial/Torsional Test Frames; Optotrak and Motion Analysis motion capture systems; Tekscan Tactile Pressure Measurement System; Custom biomechanics testing fixtures; 3-D

medical image processing software (Mimics by Materialise); engineering software (Solidworks, Labview, Matlab); and full sets of surgical instruments (Stryker, Synthes, etc.).

The Machine Shop at Genetech Hall on the UCSF Mission Bay Campus houses equipment including disk sanders, grinders, drill presses, band saws, lathes, and milling machines. Relevant equipment that can be accessed for mechanical prototyping includes lathes and milling machines to create aluminum molds for casting silicone.

Clinical Engineering Instrument Shop carries a wide array of electronic test equipment, including Tektronix 2465A and 214 oscilloscopes, digital multimeters, a Wavetek signal generator, power supplies, and various pieces audio and radio frequency test equipment. Electronic work is supported by a large selection of components and surplus equipment used for parts. The shop also has a Makita drill press, grinder, saws and a wide variety of hand and power tools for fabricating prototypes.

The Center for Advanced Technology (CAT) is a part of the Department of Biochemistry and Biophysics at the University of California, San Francisco. The primary mission is to support research labs at UCSF, but other academic and biotechnology organizations also use the facility on occasion. The center is equipped with standard research equipment such as a Q-PCR machine, a NanoDrop quantifier and plate luminometers. In addition, there is more specialized equipment such as a contact microarray printer, microwave peptide synthesizer and three-dimensional printers. They also host several pieces of cutting edge equipment including the TTP LabTech Acumen cytometer and Illumina Genome Analyzer. Their staff provides support and training for all of the resources.

The UCSF Nikon Imaging Center (NIC) is a core facility for light microscopy developed in partnership with Nikon Instruments Inc., Technical Instruments, and several other providers of microscopy instrumentation. The facility provides investigators access to microscopy resources with a particular emphasis on developing novel imaging solutions to systems biology challenges; promote cross-discipline collaborations, training, and courses; and foster collaborations with biopharmaceutical companies.

The UCSF Clinical and Translational Science Institute (CTSI) offers the Biostatistics, Research Ethics And Design (BREAD) Program to help investigators meet the methodological, statistical and ethical challenges inherent in research. BREAD services are designed to be easy to access, comprehensive, and integrated, and offer access to experts in the areas of study design and implementation, data management, biostatistics, and ethics. TTR serves multiple roles, including : providing infrastructure that enhances communication among cores and basic researchers; supporting and enhancing existing cores; improving technology education; and encouraging innovation in development of new core technologies.

The **W.M. Keck Advanced Microscopy Laboratory** specializes in developing improved light microscopes and high-resolution cryoelectron tomography and single particle methods. The Biomolecular Nanotechnology Center at UC Berkeley has equipment for the fabrication of nanoscale probes and soft-state biologic devices for measuring biological signals at the molecular and cellular level including lithography (hard and soft), etching, mask making, and thin film deposition/characterization.

The Genome Analysis Lab has an Applied Biosystems 3700 DNA sequencing capillary electrophoresis instrument, 2 Applied Biosystems 7700 quantitative real-time PCR instruments, an Applied Biosystems 7900 quantitative real-time PCR instrument, a Varian denaturing HPLC instrument, a Packard Multiprobe II liquid handling robot and a MJ Research tetrad DNA thermal cycling engine with 4 independent PCR blocks. The Applied Biosystems 3700 instrument has been the exclusive instrument for all DNA sequencing for the last 3 years. It also is used for loss of heterozygosity (LOH), SNP analysis (by Applied Biosystems SNaPshot method) and mutation analysis. The Applied Biosystems 7700 real-time PCR instruments are used for measurements of DNA copy number, RT-PCR RNA copy number, and for SNP analysis (by allele specific PCR). The Applied Biosystems 7900 is very similar to the 7700s but it accommodates plates with 384 wells (whereas the 7700s accommodate only 96-well plates), allowing higher throughput. The Varian denaturing HPLC is used for mutation analysis. The Packard Multiprobe is used to dispense multiple reagents into multiple 96 well plates and/or multiple 384 well plates for the analyses being performed by the Core. The MJ Research DNA thermal cycler can handle 96 well plates or 384 well plates.

The Core HPV, Assay and Processing Laboratories share an Applied Biosystems 7700 real-time PCR instrument, Clay Adams readacrit hematocrit centrifuge, a room temperature VanGuard clinical centrifuge, a refrigerated Sorval RC-5B, and a refrigerated Beckman Coulter Allegra 21R, a standard household refrigerator and freezer for interim (less than 24 hours) storage, a -20 freezer for long-term storage and a -70 freezer for deep freeze storage, both long-term (up to 3 months) and short term, dry ice storage for shipment of frozen specimens, and a computer primarily dedicated to specimen tracking. Colorimetric assays are read on either the 96-well plate reader (Molecular Devices Vera Max®) generously shared by the Pediatric Clinical Research Center Core Laboratory in M697 or a spectrophotometer located in another laboratory, depending on the format of each assay. The Core Assay Laboratory also has a Arcturus Laser Capture Microscope shared with the Department of Stomatology in the School of Dentistry.

ADDITIONAL OUTSIDE RESOURCES

The Bimolecular Nanotechnology Center (BNC) at the University of California, Berkeley, is an 11,500 sq ft class 1,000/10,000 cleanroom facility and a core part of the California Institute for Quantitative Biosciences, of which UCSF and UC Berkeley are a part. The BNC is a fabrication and experimentation facility specializing in BioMEMS (Biomedical Micro-electromechanical systems) and Microfluidic devices. The facility has a complete lithography microfabrication as well as soft lithography and glass or polymer bonding capabilities. The BNC features a full range of deposition, etching, metrology, and microscopy equipment as well as facilities for performing biological experiments. The center focuses on microfluidic processing of glass and polymer materials, and experimentation on proteins, nucleic acids, cells, and tissues are emphasized. In addition to a state-of-the-art research lab, the center also features a teaching lab for hands-on training of both undergraduate and graduate students. The facility is open to university and industry users allowing for unique cross-sector exposure.

The Stanford Nanofabrication Facility (SNF) is a 10,500 square foot, Class 100 cleanroom providing researchers with effective and efficient access to advanced nanofabrication equipment and expertise. A full-time staff of engineers and technicians support a complete suite of over 75 processing tools for the micro- and nano- fabrication of devices and keep the facility operational 24 hours a day, 7 days a week SNF, in partnership with thirteen other university facilities across the country including UCSF, form NSF's National Nanotechnology Infrastructure Network (NNIN), which is committed to providing nanofabrication resources to researchers across the country, in industry as well as academia. As one of the original Network sites, SNF now has over ten years of experience as an open user facility. Over 600 lab members are registered at SNF. Of the monthly average of 220 lab members who used SNF in 2009, about 15 come from non-Stanford academic institutions and 50 from industrial organizations. About 25 new researchers join SNF each month. Although more traditionally known for its strengths in silicon device fabrication, SNF has expanded its capabilities to serve other disciplines as well. Specifically, SNF now supports a large cadre of internal and external users with interests in biology, chemistry, MEMS, optics, and physics in addition to the traditional areas of electronics, materials, and process characterization. SNF lab members routinely develop processes requiring 10 to 15 or more patterning steps and hundreds of individual process steps. Thus, the SNF has extensive infrastructure for operating a large lab, training new researchers, and allowing them to fabricate complex devices.

The Taylor Collaboration is a biomechanics laboratory located at Saint Mary's Medical Center in San Francisco affiliated with the UCSF Pediatric Device Consortium. The laboratory specializes in mechanical testing of medical devices with an emphasis on orthopedic implants. The Taylor Collaboration's 1500 sq. ft laboratory contains wet lab, surgical simulation, machine and electronics shops, and materials testing areas. Staffed by mechanical and biomedical engineers, the lab contains all manner of equipment for mechanical testing of orthopedic implants, including 2- and 3-D C-arm machines; materials testing frames; 2- and 3-D motion capture systems; a full array of force, pressure, and displacement/rotation tracking sensors; a high-definition arthroscopy tower; 3-D medical image processing software (Mimics by Materialise); engineering software (Solidworks, Labview, Matlab); and full sets of surgical instruments and power tools (Aesculap & DePuy).

University of California
San Francisco

Schools of Pharmacy and Medicine
Bioengineering and Therapeutic Sciences

Shuvo Roy, Ph.D.
Professor

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San Francisco, CA 94158
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Fax: 415/ 514-9656
shuvo.roy@ucsf.edu

September 11, 2014

Zeynep Erim, Ph.D.
Program Director, Division of Interdisciplinary Training
National Institute of Biomedical Imaging and Bioengineering

Re: Candidate Eligibility Statement for Willieford Moses, MD

Dear Dr. Erim:

As Principal Investigator of the NIBIB-sponsored project "Biocompatibility of Implantable Renal Replacement Devices" (1R01 EB014315), I am writing to request a diversity supplement to this grant for the purpose of supporting the postdoctoral research training of Dr. Willieford Moses. I confirm that Willie is a U.S. citizen eligible for this supplement by virtue of his status as an underrepresented minority under the criteria listed in Section I: Recruitment and Retention to Enhance Diversity of this program announcement. Willie has not previously been supported by a PHS research grant, nor is he currently.

Willie is an extremely promising young African American surgeon-in-training whose career goal is to become an academic pediatric surgeon with an active research program in medical device innovation and development. He is eager to add an understanding of bioengineering principles to his surgical knowledge in order to effectively engage in device innovation as a faculty surgeon. The NIH and NSF have recognized that African Americans are significantly underrepresented in biomedical research. In the field of surgery this underrepresentation is particular marked. African Americans comprise a mere 2.9% of the academic surgical workface in the U.S., compared with 74.1% for whites, 10.8% for Asian Americans and 3.6% for Latino Americans (Butler et. al., Annals of Surgery, November 2008). By providing Willie with the opportunity to work on a high profile, national-scale research effort along with intensive mentoring and career development support, this supplement will give Willie an excellent foundation for future success as an independent investigator. In turn, Willie's success will contribute to elevating the status of African Americans in the medical and scientific workforce both locally and nationally.

We greatly appreciate your consideration of this application. Please do not hesitate to call me with further questions.

Sincerely,

Shuvo Roy

Shuvo Roy, PhD
Professor, Department of Bioengineering and Therapeutic Sciences
Director, Biodesign Laboratory
Director, Master of Translational Medicine Graduate Program

Institutional Official:

Sally K Brown

Sally K Brown, Contracts and Grants Officer

9/21/2010

Medicine

University of California San Francisco
Office of Admission and Registrar
500 Parnassus Ave, MU 200 West
San Francisco, CA 94143-0244

STUDENT NAME	Willieford Olatoye O. Moses	**STUDENT NUMBER**	2207
FORMER NAME			Medicine
			Fourth year
			Graduate Professional

ADMISSION CREDENTIALS			**ADMISSION DATE**	9/12/2007	**GRADUATION**
DUKE UNIVERSITY	BS	2006			
			SUBJECT A		
			AMERICAN HIST		
			AMERICAN INST		

TRANSCRIPT SUMMARY TO DATE

UNITS COMPLETED	196.50
OPT UNITS COMPLETED	0.00
GPA	0.00

Fall 07

COURSE		TITLE	UNITS	GRADE	CODE
ANATOMY	170.01	Medical Scholars Program Workshops	1.00	P	
FAM CM MED	170.10A	Homeless Health Issues	1.00	P	
INTERDEPT	101	Prologue: Topics in Anatomy, Cell Biology, Pharmacology & Radiology	9.00	P	
INTERDEPT	102A	Organ Systems: Topics in Cardiovascular Pathophysiology, Epidemiology, Pharmacology & Physiology	7.00	P	
INTERDEPT	131A	Foundations of Patient Care	3.00	P	
OB GYN R S	170.06	Disparities in African American Health	1.00	P	
PHYSIOLOGY	170.01	Medical Scholars Program Workshops	1.00	P	

TERM SUMMARY TO DATE

UNITS COMPLETED	23.00
OPT GD COMPLETED	0.00
GPA	0.00

Winter 08

COURSE		TITLE	UNITS	GRADE	CODE
FAM CM MED	170.07	Communicating with the Latino Patient	1.00	P	
INTERDEPT	102B	Organ Systems: Topics in Renal & Pulmonary Pathophysiology	9.00	P	
INTERDEPT	103A	Metabolism and Nutrition	7.00	P	
INTERDEPT	131B	Foundations of Patient Care	2.00	P	
PHYSIOLOGY	170.01	Medical Scholars Program Workshops	1.00	P	
SURGERY	160.02	OR Assist: Surgical Training for Medical Students	1.50	P	

TERM SUMMARY TO DATE

UNITS COMPLETED	21.50
OPT GD COMPLETED	0.00
GPA	0.00

Spring 08

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	103B	Metabolism and Nutrition	3.00	P	
INTERDEPT	104	Brain, Mind & Behavior: Topics in Neuroscience	12.00	P	
INTERDEPT	131C	Foundations of Patient Care	2.00	P	
SURGERY	160.03	OR Assist: Clinical Experience	.50	P	

TERM SUMMARY TO DATE

UNITS COMPLETED	17.50
OPT GD COMPLETED	0.00
GPA	0.00

Fall 08

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	105	Infection,Immunity & Inflammation: Topics in Microbiology Immunology & Pharmacology	11.00	P	
INTERDEPT	106	Mechanisms, Methods and Malignancies (M3)	10.00	P	
INTERDEPT	132A	Foundations of Patient Care	3.00	P	

TERM SUMMARY TO DATE

UNITS COMPLETED	24.00
OPT GD COMPLETED	0.00
GPA	0.00

Winter 09

COURSE	TITLE	UNITS	GRADE	CODE

9/21/2010

Medicine

INTERDEPT	107	Life Cycle: Topics in Women's & Men's Health & Pediatrics	14.00	P
INTERDEPT	132B	Foundations of Patient Care	2.00	P

TERM SUMMARY TO DATE	
UNITS COMPLETED	16.00
OPT GD COMPLETED	0.00
GPA	0.00

Spring 09

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	132C	Foundations of Patient Care	3.00	P	
OB GYN R S	110	Ob/Gyn Core Clerkship	9.00	P	

TERM SUMMARY TO DATE	
UNITS COMPLETED	12.00
OPT GD COMPLETED	0.00
GPA	0.00

Summer 09

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	111	Longitudinal Clinical Experience	1.00	P	
INTERDEPT	112	Intersession Series	1.50	P	
MEDICINE	110	Medicine Core Clerkship	12.00	H	

TERM SUMMARY TO DATE	
UNITS COMPLETED	14.50
OPT GD COMPLETED	0.00
GPA	0.00

Fall 09

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	111	Longitudinal Clinical Experience	1.00	P	
INTERDEPT	112	Intersession Series	1.50	P	
NEUROLOGY	110	Neurology Core Clerkship	6.00	P	
PSYCHIATRY	110	Psychiatry Core Clerkship	6.00	P	
SURGERY	110	Surgery Core Clerkship	12.00	H	

TERM SUMMARY TO DATE	
UNITS COMPLETED	26.50
OPT GD COMPLETED	0.00
GPA	0.00

Winter 10

COURSE		TITLE	UNITS	GRADE	CODE
INTERDEPT	111	Longitudinal Clinical Experience	1.00	P	
PEDIATRICS	110	Pediatric Core Clerkship	9.00	P	

TERM SUMMARY TO DATE	
UNITS COMPLETED	10.00
OPT GD COMPLETED	0.00
GPA	0.00

Spring 10

COURSE		TITLE	UNITS	GRADE	CODE
FAM CM MED	110	FCM Core Clerkship	9.00	H	
INTERDEPT	110	Core Clerkship in Surgical Specialties	3.00	P	
INTERDEPT	112	Intersession Series	1.50	P	
RADIOLOGY	140.09	Diagnostic Radiology at SFGH	6.00	P	
SURGERY	140.01A	Advanced General Surgery GI & Endocrine	6.00	H	
SURGERY	140.01G	Advanced General Surgery - Red Service	6.00	NR	

TERM SUMMARY TO DATE	
UNITS COMPLETED	25.50
OPT GD COMPLETED	0.00
GPA	0.00

Summer 10

COURSE		TITLE	UNITS	GRADE	CODE
SURGERY	140.22	Advanced Trauma / General Surgery	6.00	H	

TERM SUMMARY TO DATE	
UNITS COMPLETED	6.00
OPT GD COMPLETED	0.00
GPA	0.00

9/21/2010

Medicine

MEMO

UCSF
University of California
San Francisco

TRANSCRIPT of STUDENT ACADEMIC RECORD

Enrolled prior to Fall Quarter 1978 – Photocopy of hard copy or microfiche

Enrolled Fall Quarter 1978 or thereafter – Computer-generated transcript

Each quarter or term contains the following columns in left-to-right order: department, course number, title, units, grades, and codes (course titles are included beginning with Fall Quarter 2001).

GRADES IN GRADUATE DIVISION AND SCHOOLS OF DENTISTRY, NURSING, AND PHARMACY		
Grade	*Points*	*Meaning*
A	4.0	**Excellent**
B	3.0	**Good**
C	2.0	**Fair**
D	1.0	**Barely Passing**
F	0.0	**Fail**
H	–	**Honors.** Awarded in third and fourth year. *(Dentistry)*
Y	–	**Provisional grade.** Denotes a provisional non-passing grade. May be raised to a **D** if requirements are met, or changed to grade **F.**
	0.0	*(Pharmacy)*
I	–	**Incomplete.** Assigned when work is of passing quality but incomplete for good cause. Students may replace this grade with a passing grade and receive unit credit, provided they satisfactorily complete the coursework as authorized by the instructor.
IP	–	**In Progress.** For courses extending beyond one quarter.
P/NP	–	**Passed / Not Passed** *(Dentistry and Pharmacy)*
S/U	–	**Satisfactory / Unsatisfactory** *(Graduate and Nursing)*
SP/UP	–	**Satisfactory / Unsatisfactory Progress** *(Dentistry)*
NR	–	**Not Recorded**
GRADES IN SCHOOL OF MEDICINE		
P	–	**Passed**
H	–	**Honors.** Awarded in third and fourth year for courses of three or more units in summer term 1992 or later.
I	–	**Incomplete** *(See description above)*
IP	–	**In Progress** *(See description above)*
E	–	**Provisional grade.** A provisional non-passing grade.
F	–	**Fail.** Grade F is a permanent grade.
NR	–	**Not Recorded**

CODES	CODE DESCRIPTIONS
C	Correction
G	Grade assigned, sequence completed
N	Provisional grade removed
R	Repeated course *(Dentistry and Pharmacy)*
S	Used when student is required by the dean to repeat a year, a term, or specific courses. Suppresses grade and units from calculation.
T	Repeat. Suppresses units from calculation.
X	Credit by examination
2	Intercampus exchange
7	Consortium course
W	Withdrew from all courses in the term

ACADEMIC STANDARDS FOR STUDENTS

STANDARDS OF SCHOLARSHIP

Graduate Students. Only grades of **A, B, C,** or **S** are counted toward satisfaction of degree requirements. A maximum of 6 units in which **S/U** grading is elected may be counted toward the minimum unit requirement for a graduate degree. Graduate students must maintain a minimum grade point average (GPA) of 3.0 in all upper-division and graduate courses.

Dentistry and Pharmacy Students. Grades of **A, B, C, D,** and **P** are counted toward satisfaction of degree requirements. Dentistry and Pharmacy students must maintain a minimum 2.0 cumulative GPA.

COURSE NUMBERING SYSTEM

100 = Upper-division undergraduate and professional courses.
200 & 300 = Graduate academic courses.
400 = Post-doctoral and professional school clinical courses.

REPETITION OF COURSES

Unless authorized by the dean, and except for courses normally offered for repeat credit, students may repeat only courses in which they received a **D, F,** or **NP.** Except by dean's permission, students may not repeat a course more than once for which they originally received a grade of **D, F,** or **NP.** When a course is repeated, the units are credited toward the degree only once. A student's grade point average is computed quarterly and cumulatively on the total number of units attempted and completed (successfully or unsuccessfully).

FULL-TIME STUDENTS

Dentistry, Medicine, and Pharmacy students must be enrolled full time.

PART-TIME STUDENTS

Graduate Division and Nursing students who meet certain criteria may apply for part-time status.

WITHDRAWAL

A registered student who withdraws, is dismissed, or is absent without leave from the University before the end of the term may receive a grade of **F** or **NP** for each course in which he/she is enrolled.

ACCREDITATION

The University of California, San Francisco is accredited by the Western Association of Schools and Colleges.

PRIVACY NOTICE

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University of California, San Francisco
Office of Admission and Registrar
500 Parnassus Avenue, MU-200W
Box 0244
San Francisco CA 94143-0244
Tel. (415) 476-4356 • Fax (415) 476-9690
http://saawww.ucsf.edu/admission/transcript.html

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- Touch, rub, or breathe on TouchSafe® fingerprint verification seal to see hidden message "VALID".
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Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Regents of the University of California, San Francisco
Duns Number:	0948783370000
Street1*:	1700 4th Street, Room 203A
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94158-2520
Project/Performance Site Congressional District*:	CA-012

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

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Project/Performance Site Congressional District*:	CA-012

File Name

Additional Location(s)