EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF NURSING RESEARCH

Grant Number: 1R21NR014349-01A1
FAIN: R21NR014349

Principal Investigator(s):
SALLY L MALISKI, PHD
Jeffrey Lorne Veale (contact), MD

Project Title: A Mixed Methods Approach to Understand Donor Choice

Ms. Duiker, Kim
Assistant Director
11000 Kinross Avenue, Suite 211
Los Angeles, CA 900951406

Award e-mailed to: NIHaward@research.ucla.edu

Budget Period: 05/01/2014 – 04/30/2015
Project Period: 05/01/2014 – 04/30/2016

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $231,000 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute Of Nursing Research of the National Institutes of Health under Award Number R21NR014349. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with 42 CFR Part 50 Subpart F. Subsequent to the compliance date of the 2011 revised FCOI regulation (i.e., on or before August 24, 2012), Awardees must be in compliance with all aspects of the 2011 revised regulation; until then, Awardees must comply with the 1995 regulation. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,
Kelli Oster
Grants Management Officer
NATIONAL INSTITUTE OF NURSING RESEARCH

Additional information follows
SECTION I – AWARD DATA – 1R21NR014349-01A1

Award Calculation (U.S. Dollars)

Federal Direct Costs $150,000  
Federal F&A Costs $81,000   
Approved Budget $231,000  
Federal Share $231,000  
TOTAL FEDERAL AWARD AMOUNT $231,000

AMOUNT OF THIS ACTION (FEDERAL SHARE) $231,000

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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
CFDA Number: 93.361
EIN: 1956006143A1
Document Number: RNR014349A
PMS Account Type: P (Subaccount)
Fiscal Year: 2014

IC CAN 2014 2015
NR 8472497 $231,000 $192,500

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
Award Processed: 03/04/2014 08:59:52 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R21NR014349-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R21NR014349-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase V Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.
An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21NR014349. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/

Treatment of Program Income:
Additional Costs

SECTION IV – NR Special Terms and Conditions – 1R21NR014349-01A1

REQUIREMENT: This grant has multiple Principal Investigators (PIs). In accordance with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), although the signatures of the PIs are not required on prior approval requests submitted to NINR, the grantee institution must secure and retain the signatures of all the PIs in accordance with their institutional policy.

INFORMATION: MODULAR GRANT AWARD
This is a modular grant award without direct cost categorical breakdown in accordance with the guidelines published in the NIH Grants Policy Statement (revised October 2013) (see http://grants.nih.gov/grants/policy/nihgps_2013/index.htm). Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

INFORMATION: NINR ADJUSTMENTS FOR SALARY BASED AWARDS:
Salary funds provided on NINR research grants will be adjusted if investigators receive career-type salary based awards. In the event that such an award is made for an investigator receiving salary support from an NINR grant, the National Institute of Nursing Research must be informed in writing within 30 days from the start date of the award so that any required adjustment can be made.

INFORMATION: HUMAN SUBJECTS EDUCATION CERTIFICATION
This award reflects the National Institute of Nursing Research acceptance of the certification that all key personnel as defined in the February 28, 2008 NIH Guide announcement (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html) have completed education on the protection of human subjects, in accordance with NIH policy requirements. Any key personnel, as defined in that announcement, must satisfy this requirement prior to participating in

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the project. Failure to comply can result in suspension and/or termination of this award or withholding of support of the continuation award.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Lawrence R Haller
Email: hallerl@mail.nih.gov  Phone: 301-402-1878  Fax: 301-451-5652

Program Official: Karen Huss
Email: hussk@mail.nih.gov  Phone: 301.594.5970  Fax: 301.480.8260

SPREADSHEET SUMMARY
GRANT NUMBER: 1R21NR014349-01A1

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

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**PI:** Veale, Jeffrey Lorne  
**Title:** A Mixed Methods Approach to Understand Donor Choice

- **Received:** 07/16/2013  
- **FOA:** PA11-261  
- **Council:** 01/2014

**Competition ID:** ADOBE-FORMS-B2  
**FOA Title:** NIH EXPLORATORY/DEVELOPMENTAL RESEARCH GRANT PROGRAM (PARENT.R21)

**1 R21 NR014349-01 A1**  
**Dual:**  
**Accession Number:** 3610528

**IPF:** 577505  
**Organization:** UNIVERSITY OF CALIFORNIA LOS ANGELES

**Former Number:**  
**Department:** Urology

**IRG/SRG:** NRCS  
**AIDS:** N  
**Expedited:** N

**Subtotal Direct Costs**  
(excludes consortium F&A)  
- **Year 1:** 150,000  
- **Year 2:** 125,000

**Animals:** N  
**Humans:** Y  
**Clinical Trial:** N  
**Current HS Code:** 30  
**HESC:** N

**New Investigator:** N  
**Early Stage Investigator:** N

**Senior/Key Personnel:**  
**Organization:**  
**Role Category:**

- **Jeffrey Veale MD**  
  Regents of the University of California, Los Angeles  
  PD/PI

- **Sally Maliski PhD.**  
  Regents of the University of California, Los Angeles  
  MPI

- **Amy Waterman PhD**  
  Washington University in St. Louis  
  Consultant

**Appendices**

- appendix_b_donors_qualitative_interview1024836163
- appendix_a_donor_demographics102483616
APPLICATION FOR FEDERAL ASSISTANCE  
SF 424 (R&R)

1. * TYPE OF SUBMISSION  
   ☑ Pre-application  ☐ Application  ☐ Changed/Corrected Application

2. DATE SUBMITTED  
   07/16/2013

   Applicant Identifier

3. DATE RECEIVED BY STATE

4. a. Federal Identifier
   MRG143149

   b. Agency Routing Identifier

5. APPLICANT INFORMATION
   * Organizational DUNS: 092330369
   * Legal Name: Regents of the University of California, Los Angeles
   Department: Office of Contract & Grant Admin
   Division:
   * Street1: 11000 Kinross Avenue, Suite 211
   Street2:
   * City: Los Angeles
   County/Parish: Los Angeles County
   * State: CA
   Province:
   * Country: USA
   ZIP/Postal Code: 90095-1406

   Person to be contacted on matters involving this application
   Prefix: Ms.
   * First Name: Kim
   Middle Name:
   Last Name: Kuiper
   Suffix:
   * Phone Number: 310-794-0165
   Fax Number: 310-943-1658
   Email: ocgs5research.ucla.edu

6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): 1-956006143-A1

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):

   * 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:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
   Altruistic Kidney Donation: A Mixed Methods Approach to Understand Donor Choice

12. PROPOSED PROJECT:
   * Start Date: 04/01/2014  * Ending Date: 03/31/2016  CA-033

13. CONGRESSIONAL DISTRICT OF APPLICANT

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
   Prefix: Dr.
   * First Name: Jeffrey
   Middle Name:
   Last Name: Veale
   Suffix: MD
   Position/Title: Assistant Professor
   * Organization Name: Regents of the University of California, Los Angeles
   Department: Pathology
   Division:
   * Street1: Box 951738
   Street2: 66-138A CHS
   * City: Los Angeles
   County/Parish: Los Angeles County
   * State: CA
   Province:
   * Country: USA
   ZIP/Postal Code: 90095-7309
   * Phone Number: 310-253-3495
   Fax Number: 310-2065343
   * Email: jveale@mednet.ucla.edu

Tracking Number: GRANT1451384  Funding Opportunity Number: PA-11-261 Received Date: 2013-07-16 T19:27:10-04:00
15. ESTIMATED PROJECT FUNDING

| a. Total Federal Funds Requested | 423,500.00 |
| b. Total Non-Federal Funds       | 0.00       |
| c. Total Federal & Non-Federal Funds | 423,500.00 |
| 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 actions 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. SFLLI or other Explanatory Documentation

19. Authorized Representative

Prefix: Ms.  * First Name: Kim  Middle Name: 
* Last Name: Duiker  Suffix: 
* Position/Title: Assistant Director

* Organization: Regents of the University of California, Los Angeles

Department: Office of Contract & Grant Admin  Division: 
* Street: UCLA Office of Contract & Grant Admin

Street 2: 11000 Wexford Avenue, Suite 211

* City: Los Angeles  County/Parish: Los Angeles

* State: CA: California  Province: 
* Country: USA: UNITED STATES  * ZIP/Postal Code: 90095-1406

* Phone Number: 310-794-0160  Fax Number: 310-943-1658

* Email: ocsa9research.ucla.edu

* Signature of Authorized Representative

Kim Duiker

* Date Signed

07/16/2013
# 424 R&R and PHS-398 Specific Table Of Contents

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**Appendix**

*Number of Attachments in Appendix: 2*
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: Regents of the University of California, Los Angeles

DUNS Number: 0925303690000

* Street1: 10833 Le Conte Avenue

Street2: 3361 PVUB

* City: Los Angeles

County: Los Angeles County

* State: CA: California

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 90095-7309

* Project/Performance Site Congressional District: CA-033

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.

Organization Name: Regents of the University of California, Los Angeles

DUNS Number: 0925303690000

* Street1: 10833 Le Conte Avenue

Street2: 2-256 Factor Bldg.

* City: Los Angeles

County: Los Angeles County

* State: CA: California

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code: 90095-6918

* Project/Performance Site Congressional District: CA-033

Additional Location(s)
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:  02/21/2012

Human Subject Assurance Number:  00004642

2. Are Vertebrate Animals Used?  ☐ Yes  ☒ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?  ☐ Yes  ☒ No

IACUC Approval Date:  

Animal Welfare Assurance Number:  

3. Is proprietary/privileged information included in the application?  ☒ Yes  ☐ No

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - 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

5.a. If yes, please explain:  

6. Does this project involve activities outside of the United States or partnerships with international collaborators?  ☒ Yes  ☐ No

6.a. If yes, identify countries:  

6.b. Optional Explanation:  

7. Project Summary/Abstract  Project_Summary1024836147.pdf  Add Attachment  |  Delete Attachment  |  View Attachment

8. Project Narrative  Project_Narrative1024836148.pdf  Add Attachment  |  Delete Attachment  |  View Attachment

9. Bibliography & References Cited  References_2013_07_161024954932.pdf  Add Attachment  |  Delete Attachment  |  View Attachment

10. Facilities & Other Resources  Facilities1024836169.pdf  Add Attachment  |  Delete Attachment  |  View Attachment

11. Equipment  Add Attachment  |  Delete Attachment  |  View Attachment

12. Other Attachments  Add Attachments  |  Delete Attachments  |  View Attachments  |  

Other Information  

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Project Summary
Kidney donation is life-saving for those with end-stage renal disease, providing the possibility of a relatively healthy and productive life. Unfortunately, there is a severe deficit in the number of donor kidneys relative to the number of patients in need. A novel approach to this situation has been the creation of transplantation chains triggered by non-directed (altruistic) donors. Transplantation chains are initiated when a non-directed (altruistic) donor donates a kidney to a patient who has a willing but incompatible donor. Once this recipient is transplanted, his or her original willing-incompatible donor – known as a bridge donor – then passes on the generosity to another recipient. Once the second recipient receives a transplant, their original incompatible donor likewise passes on the generosity to a third recipient. This process can be repeated for multiple iterations creating long chains of transplantations. The patients who receive transplants as part of chains are removed from the deceased donor waiting list, enabling other candidates to move up the waiting list and take their spots. This approach has potential to decrease the competition for deceased donor organs, easing the strain on the waiting list. Yet, very little is known about how non-directed (altruistic) donors and bridge donors make decisions about donating a kidney, nor about characteristics of potential donors who actually donate versus those who do not complete the donation process. Emerging themes from our pilot study suggest a need to further investigate the emotional journey of donors, especially post transplant. Striking patterns between donor demographics, strong health and quality of life outcomes, and specific beliefs are apparent. Therefore, this study utilizes a qualitative-dominant mixed methods approach to develop an explanatory framework for the decisional processes of non-directed donors and bridge donors. People who considered becoming non-directed (altruistic) donors or bridge donors but eventually decided against donating as well as actual non-directed (altruistic) donors and bridge donors will be recruited. Participants will complete an in-depth interview as well as quantitative measures of health related quality of life, anxiety, and depression. The development of the interview guide and selection of the quantitative measures will be informed by an advisory board of stakeholders in the kidney transplant community, including kidney donors and recipients, family members of kidney donor recipients, kidney donation advocates, and representatives from transplant registries. In an effort to ultimately expand the donor pool, results from this study will be the first to provide an in-depth description of potential and actual altruistic kidney donors that will provide the foundation upon which to develop educational materials for individuals contemplating kidney donation, create and test tools to identify those most likely to be successful altruistic donors, and to develop concepts and hypotheses to further explore this new and innovative phenomena.
Project Narrative
The need for kidney transplants is overwhelmingly larger than the supply of donor organs, but kidney donation chains triggered by altruistic donors offer an innovative solution to this problem. This study will develop a better understanding of the decisional processes of chain kidney donors in order to develop educational materials for individuals contemplating kidney donation and create and test tools to identify those most likely to be successful altruistic donors in order to increase the living donor pool and the quality of the donation experience.
Facilities and other Resources
The research team brings exceptionally strong credentials to the proposed project. In addition to the substantive expertise and experience on which we will capitalize during the project, we will draw on the superb infrastructures at each institution to support the proposed work. Below we highlight the institutions’ research capabilities and support systems.

UCLA
UCLA is an academic and research institution committed to addressing the challenges of global research issues in areas such as human health, the environment, energy, water and food supply, technologies for wealth and job creation, and quality of life. UCLA works in mutually profitable partnerships with many constituencies: universities, government, private industry, philanthropic organizations, and others. The intellectual contributions made by the prestigious faculty provide a strong foundation for a project of this magnitude.

Primary UCLA Resources.

UCLA Department of Urology. Since its inception in 1951, the Department of Urology has focused on exemplary patient care, pioneering clinical and basic research, and undergraduate and graduate medical education. The UCLA Department of Urology consistently ranks in the top five urology programs in the nation as rated by the U.S. News and World Report. It ranks first in NIH funding among urology departments nationally. The faculty includes world renowned experts in all urologic subspecialties. Select specific specialty topic areas are described below. Its website may be viewed at www.uclaurology.com.

Urological Health Services Research. Determining effective treatment options for common urologic ailments is a particularly important issue in the realm of managed health care. Urologic health services research, established at UCLA in 1993 with the recruitment of Dr. Mark S. Litwin, brings a unique perspective to the practice of urology—that of the psychosocial, sociopolitical, and health policy aspects of urologic care. In collaboration with the UCLA School of Public Health and the JCCC, Dr. Litwin has developed an internationally recognized research program that considers medical outcomes, quality of care, health-related quality of life, costs of urologic diagnosis and treatment, and urologic resource utilization in the United States. Since his arrival at UCLA, Dr. Litwin has attracted more than $90 million in peer-reviewed research grants as principal investigator. This research in the translational population sciences ultimately impacts quality of care and cost-efficiency in our nation’s health care system.

Kidney Cancer Program. The Kidney Cancer Program was established at UCLA in 1982. This program offers patients both standard and innovative experimental therapies that use novel biologic response modifiers. Dr. Arie Beldegrun, Professor of Urology and Director of the Division of Urologic Oncology, leads a multidisciplinary team of specialists in medical oncology, urology, cardiology, pulmonary medicine, endocrine medicine, nephrology and infectious diseases. Diagnostic radiologists play an important role in performing and reviewing x-rays and CT scans, while radiation oncologists treat patients requiring palliation for advanced disease. The Kidney Cancer Program calls on the expertise of its dedicated staff to develop treatment plans tailored to meet the individual needs of each patient. All team members participate in designing each patient treatment plan.

The goals of the Kidney Cancer Program include involving patients with cutting-edge research studies as well as standard therapies and providing superior comprehensive care to patients. Patient education is also a top priority. The Kidney Cancer Program sponsors monthly educational seminars on kidney cancer.

The Kidney Cancer Program sees over 2,000 patients per year. Patients come to the program either by self-referral or physician referral. The staff of the Kidney Cancer Program has published numerous articles on their treatment outcomes and research and has presented numerous lectures about kidney cancer at national and local professional conferences.

Renal Transplantation. In the 1960s, Dr. Willard E. Goodwin, founder of UCLA Urology pioneered the first renal transplants in the Western United States. Today, the field of renal transplantation is characterized by a close working relationship with the UCLA Department of Nephrology. From its first director, Dr. J. Thomas
Rosenthal, to his successor, Dr. H. Albin Gritsch, the Renal Transplant Program has been highly successful, achieving one of the lowest organ rejection rates in the country. Overall, the Renal Transplant Program completes 300 transplants a year; in its history it has completed over 6,000 kidney transplants. The UCLA Donor Exchange Program, directed by Dr. Jeffrey Veale, is one of the largest in the country consistently achieving the best outcomes. The program is poised to complete its 100th donor exchange transplant by the end of July 2013.

**UCLA School of Nursing.** The Office of Research at the UCLA School of Nursing includes the Associate Dean of Research (Sally Maliski, PhD, RN); Director of Research (Priscilla Kehoe, PhD); Director of Design and Data Core (Mary-Lynn Brecht, PhD) and three more statisticians; a Director of Research Administration (Rokas Oginskis) and three Senior Contract and Grant Analysts, a Research Purchasing Assistant, and an IRB Specialist. The Office of Research has two important goals: a) to promote and facilitate faculty research intramural and extramural funding, and student scholarship; and b) to promote and facilitate interdisciplinary and international scholarship.

These goals are reflected in a number of activities. The Office of Research staff addresses the research methodology needs of the School including: statistical and programming consultation; research design and methodology consultation; and mock reviews of project specific aims, grants, and manuscripts. Another set of activities run by this office address the maintenance and flow of information concerning grants, fellowships, contracts, human subject and scientific integrity policies, and psychometric instruments on file in the School. Research and scholarship among faculty and students is promoted through an Annual Graduate Student and Faculty Research Day, grant and proposal writing workshops, review and critique of grant proposals, rehearsals for site visits, monthly research seminars for presentation of faculty research and to discuss related research topics. As needed, faculty and students may request special colloquia to address special research topics of interest to faculty and students. The Office of Research also maintains a database of faculty research interest and expertise for use by others outside of the School. The Associate Dean for Research meets with Deans of Research from other schools and with Directors of Nursing Research in clinical centers to explore avenues for collaboration with School of Nursing faculty, facilitates faculty and student participation in research events outside the School, and assists with the development and selection of clinical sites for the conduct of research. The Director of Research provides mentorship for faculty and students for grant writing and manuscript preparation, organizes the Annual Graduate Student and Faculty Research Day, and facilitates the "Brown Bag Seminars" (monthly lunchtime research seminars). The statistical support team provides services for statistical consultation and analyses, data management, and data entry.

The UCLA Office of Contract and Grant Administration (OCGA) supports the School of Nursing’s research initiatives by reviewing grant proposal content and budgets for accuracy and compliance. Extramural grant proposals are submitted to the potential funding agencies via the UCLA OCGA. This office also facilitates progress reports, project extensions and the award processes.

**School of Nursing Information Technology Infrastructure for Research**

The School of Nursing Computing Information Technology Office currently provides a broad range of advanced technical services to research grants run under the auspices of the UCLA School of Nursing to further the school’s strong focus on research.

Nearly all research activities in the School of Nursing now make use of network-based file storage and backup, and utilize modern computer workstations and advanced statistical software. In addition, connectivity via the school’s high-speed network allows faculty and grant users to access online research resources throughout UCLA and the Internet. Productivity software, email, and anti-virus software are provided free of charge, and a website is maintained for the purpose of disseminating school and grant research information to peers and the public. Common grant preparation software (such as the online PureEdge portal, Adobe Acrobat Writer, etc.) is downloaded and installed on faculty and staff’s computers. Also, due to the sensitive nature of research data, the Information Technology Office maintains extensive security systems to monitor for viruses, scan for intruders, and protect user data and systems from compromise or damage.
Overall, the Information Technology Office works to make information technology accessible and secure for researchers in the School of Nursing, and provide the technology support needed to maintain the school's tradition of research excellence.

**California Living-Donor Registry**
The California Living-Donor Registry was founded in 2010 by state legislation and is the first living donor registry in the world. It is a non-profit organization aimed at promoting and assisting with live kidney donations, with a particular focus on kidney exchanges and non-directed donations. Dr. Veale and two members of the Advisory Committee have been involved in this resource's development, and the organization's website is slated to go live in the fall of 2012. The website will provide resources for those interested in donating a kidney, and has been vetted and supported by kidney transplant programs statewide.
## RESEARCH & RELATED Senior/Key Person Profile (Expanded)

### PROFILE - Project Director/Principal Investigator

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<tr>
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<td>E-Mail</td>
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### PROFILE - Senior/Key Person 1

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<tr>
<td>Dr.</td>
<td>Sally</td>
<td></td>
<td>Maliiski</td>
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### Attach Biographical Sketch

Veale_Biosketch_2013_07_1610.pdf

### Attach Current & Pending Support

Maliiski_Biosketch1024836061.pdf
RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Senior/Key Person 2

Prefix: 
* First Name: Amy
Middle Name: D.
* Last Name: Waterman
Suffix: PhD
Position/Title: Assistant Professor
Department: School of Medicine
Organization Name: Washington University in St. Louis
Division: Internal Medicine
* Street1: 660 S. Euclid Avenue
Street2: 
* City: St. Louis
County/Parish: 
* State: MO: Missouri
* Country: USA: UNITED STATES
* Zip / Postal Code: 63110-1010
* Phone Number: 314-747-9212
Fax Number: 888-617-4513
* E-Mail: amywaterman@wustl.edu
Credential, e.g., agency login: PRA Common User Name
* Project Role: Consultant
Other Project Role Category: 
Degree Type: PhD
Degree Year: 2001
*Attach Biographical Sketch Waterman_Biosketch1024836990
Attach Current & Pending Support

Key Personnel
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
Veale, Jeffrey L, MD, BSc, FRCSC

POSITION TITLE
Director, Kidney Transplant Exchange Program

INSTITUTION AND LOCATION  DEGREE  MM/YY  FIELD OF STUDY
University of Calgary  BSc  05/97  Zoology
University of Calgary  MD  05/00
University of Manitoba  FRCSC  04/05  Urology Residency
University of California, Los Angeles  05/07  Surgical Fellow - Renal Transplantation

A. Personal Statement

The goal of this project is to better understand the decision processes of potential and actual altruistic kidney donors. Improving navigation of the many complex factors surrounding renal transplantation, including donor matching, donation chains, and graft monitoring, is my life's work. Although my academic career has not been long, it has already been productive and rewarding. As the director of the Kidney Transplant Exchange Program at UCLA, I encounter the selfless gift of kidney donation every day. It is these stories which have galvanized my collaboration with Dr. Maliski. Collaboration with her experienced research team has produced two submitted manuscripts, one poster presentation, and two accepted oral presentation abstracts which explore the social context of kidney donation. Sadly, there are not enough kidneys to go around. With this work I hope to gain knowledge that may help to remedy this unfortunate gap. In the past, I have worked to improve the kidney transplantation process through better detection and tracking of potential graft rejection, as well as through the improvement and expansion of donation exchanges and donation chains. I have worked with several national and regional kidney donation programs and committees; I am currently the Chair of the Surgery Committee for the National Kidney Registry (NKR) and on the Advisory Board for Living Donation California. As the PI of this project, I will leverage my positions in these organizations and in the UCLA Kidney Transplant Exchange Program to access individuals considering donating altruistically. I will also use the expertise I have gained in my years of work with kidney donors, including performing the first chain transplantation from an altruistic donor that was shipped unaccompanied via commercial airline, performing the first out-of-sequence-asynchronous altruistic donor chain, and participation in the longest kidney donation chain to date. This clinical acumen will be essential during the design, execution, and analysis of this important work.

B. Positions and Honors

Positions and Employment
2006-2007  Visiting Assistant Professor, Department of Urology, UCLA
2007-2013  Assistant Professor, Department of Urology, UCLA
2007-Present  Director, Kidney Transplant Exchange Program, UCLA
2013-Present  Associate Professor, Department of Urology, UCLA

Invited Visiting Professorships
November 2010  Barcelona, Spain
(Fundacio-Pulvert) Organizacion Nacional de Trasplantes (ONT):
VII Curso Teorico-Practico de Formacion en Transplante Renal de Donante Vivo,
"Trasplante renal con cadenas de intercambio de donantes".

April 2012  Quebec City, Canada
University of Laval, Department of Urology
Kidney Transplantation Program

Other Experience and Professional Memberships
Member, American Society of Transplant Surgeons
Member, American Society of Transplant
Member, American Urological Association
Member, Canadian Urological Association
Fellow of the Royal College of Surgeons (Canada)
Member, Medical Board of California
Member, Urologic Society for Transplantation / Renal Surgery
Member, UNOS Kidney Paired Donation Pilot Program Strategic Planning Team
Member, OPTN/UNOS Kidney Paired Donation Subcommittee on Chains
Chair, National Kidney Registry Surgical Committee
Executive Committee Member, National Kidney Registry
Medical Advisory Board Member, National Kidney Registry
Board of Advisors, Living Donation California
OneLegacy Kidney and Pancreas Committee
UCLA Department of Urology Finance Committee
UCLA Kidney and Pancreas Transplantation Program Committee
UCLA Kidney Transplant Executive Committee
UCLA Faculty Practice Group – Surgical Services Committee
UCLA Academic Senate - Committee on Intercollegiate Athletics

Honors
2004  Daisy Pin Award, St. Boniface General Hospital
2005  Urology Resident Research Award, University of Manitoba
2005  David Schwartz Memorial Award, University of Manitoba
2006  William P. Longmire Award, UCLA
2009  New Key Opinion Leader, Transplantation Society
2009  Medical Innovator of the Year Award, National Kidney Registry
2009  Graduate of the Decade (Gold) Award, University of Calgary
2012  Teaching Humanism at the Bedside Award, UCLA

C. Selected Peer-reviewed Publications (Selected from 21 publications and 5 book chapters)


7. Shah GJ, Veale JL, Korin Y, Reed EF, Gritsch HA, Kim CJ. Specific binding and magnetic concentration of CD8+ T-lymphocytes on electrowetting-on-dielectric platform. BIOMICROFLUIDICS, 2010 November (published online – print version to follow)


12. Wei F, Chen S, Korin Y, Reed E, Gjertson D, Ho CM, Gritsch HA, Veale J. Direct Serum Creatinine Detection by a Conducting Polymer Based Electrochemical Sensor to Identify Allograft Dysfunction. ANALYTICAL CHEMISTRY. 2012 August 10; (Epub ahead of print).


D. Research Support

**Ongoing Research Support**

| Private Source | Veale (PI) | 01/01/2008 – present (Open-ended) |

**Completed Research Support**

| UL1TR000124 | Veale (PI) | 04/01/2012 – 11/01/2012 |

Monitor Renal Allograft Dysfunction by a Multiplexing Electrochemical Sensor for Combinational Biomarkers: Creatinine and Cystatin-C

The purpose of this study is to begin development of a rapid/accurate POCT device for measuring creatinine and cystatin-C levels in the whole blood.

Role: PI
R43 DK085783    Rubtsov (PI)    05/01/2010 - 04/30/2011
Surgical Instrument Guide-MEMS (SIG-MEMS)
The goal of this study is to optically produce two spatially separated images and perform a triangulation calculation, but will use only one imaging channel — unlike conventional stereo-devices, which can be bulky and use two channels. The small dimensions and light-weight of this sensor can be incorporated into a smaller surgical tool.
Role: Co-I

R43 RR030712    Rubtsov (PI)    04/01/2010 - 01/31/2011
Measuring Endoscopic Probe
The proposed device will be used for tracking a surgical instrument within a human body, via noncontact, passive, optical rangefinding. It will provide information on distances between an organ and an approaching instrument tip, and will feed this information back to the surgeon.
Role: Co-I

U19AI063603    Salomon (PI)    09/01/2004 - 08/31/2011
Genomics for Kidney Transplantation
The objective is to establish the gene expression profiles, tandem mass spectrometry proteomics profiles, and SNP genotypes of transplant biopsies and Peripheral Blood Lymphocytes of transplant patients correlating with specific clinical phenotypes.
Role: Key Contributor
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
Sally L. Maliski, RN, PhD

POSITION TITLE
Associate Professor

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

<table>
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<tr>
<td>State University of New York, Albany, NY</td>
<td>BS</td>
<td>1971-1976</td>
<td>Nursing</td>
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<td>Russell Sage College, Troy, NY</td>
<td>MS</td>
<td>1977-1980</td>
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<td>University of North Carolina at Chapel Hill, Chapel Hill, NC</td>
<td>PhD</td>
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<td>University of California at Los Angeles, Los Angeles, CA</td>
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A. Personal Statement

I have used a variety of qualitative methods, quantitative methods, and interventionist approaches to investigate how context plays a role in cancer prevention, treatment, and survivorship. For the last fifteen years I have been committed to research which alleviates health disparities, facilitates symptom management, and promotes quality of life. I have over ten years experience conducting research with minority, low income men treated for prostate cancer with various modalities. My expertise in qualitative methods and my experience directing complex, team-based qualitative projects on two Department of Defense grants and three NIH grants will anchor the research team methodologically. I have often reached beyond patients affected by disease to incorporate their families and communities as research participants to better understand decision making, promote health education, and create culturally appropriate recommendations and interventions. My sensitivity to context is critical to studying the social networks and human impact of kidney donation and donation chains. My socio-cultural and health services lens will complement Dr. Veale’s expertise in kidney transplantation. Our team has already produced two manuscript submissions, one poster presentation, and As Associate Dean of Academic Affairs and Associate Professor in the UCLA School of Nursing with a joint appointment in the Department of Urology in the David Geffen School of Medicine, I have enjoyed a collaborative relationship with physicians, surgeons, and clinical researchers for many years, especially in the area of urologic cancers. This track record of successful interdisciplinary leadership is a strong foundation for my work with Dr. Veale.

B. Positions and Honors

**Positions and Employment**

- 1976-1980 Staff and Head Nurse, Veterans Administration Medical Center, Albany, NY
- 1979-1984 91C Medical Corpsmen Course Director, Army Reserve Nurse Corps, 364th General Hospital, Albany NY
- 1980-1981 Assistant Professor, Columbia Memorial Hospital School of Nursing, Hudson, NY
- 1981-1985 Patient Care Coordinator, Hospice of Schenectady, Schenectady, NY
- 1985-1987 Assistant Professor, Columbia Memorial Hospital School of Nursing, Hudson, NY
- 1989-1996 Research Assistant, University of North Carolina, Chapel Hill, NC
- 1996-1997 Instructor, University of North Carolina, Greensboro, NC
- 1997 Assistant Professor, Rutgers University, Newark, NJ
- 1998-1999 Research Associate, University of Pennsylvania, Philadelphia, PA
- 2001-2004 Assistant Researcher, University of California, Los Angeles, CA
- 2004-2011 Clinic Coordinator, Westminster Free Clinic, Thousand Oaks, CA

Biographical Sketches for each listed Senior/Kay Person 2. Page 17
2005-2011. Assistant Professor, University of California, Los Angeles, CA
2011-present. Associate Professor, University of California, Los Angeles, CA
2012-present. Associate Dean for Academic Affairs, University of California, Los Angeles, CA

Other Experience and Professional Memberships
1976-present. Sigma Theta Tau
1980-present. Oncology Nursing Society
2003. Reviewer, ONS/Schering Excellence in Cancer Nursing Award
2003-present. Peer reviewer, Nursing Research, Patient Education and Counseling, Psycho-Oncology,
Supportive Care in Cancer, Cancer Nursing, European Journal of Clinical Care, Health Risk
and Society, and Oncology Nursing Forum
2004. Reviewer, 8th National Conference on Cancer Nursing Research
2004-2005. ONS National Survey Project Team on Nursing Research Priorities
2006-2009. Reviewer, ONS Small Grants Program
2007-2009. Member, APHA
Grant, Social Sciences and Humanities Research Council of Canada Grant
2009-present. Member, Board of Directions for California IMPACT program.
2011. Ad Hoc reviewer Department of Defense Prostate Cancer Research Program
2011. External Reviewer, University of Colorado, College of Nursing
2011. Member, Yale-China Association

Honors
1987-1989. Merit Assistantship, University of Nursing Carolina, Chapel Hill.
2001. Recipient, ONS/Schering Excellence in Cancer Nursing Research Award
2005. Nominee, ONS/Schering Excellence in Cancer Nursing Research Award
2010. Fellow in the American Academy of Nursing

C. Selected Peer-reviewed Publications (Selected from a total of 43 papers and 2 chapters)

1. Maliski SL, Heilemann MV, McCorkle R. Mastery of postprostatectomy incontinence and impotence: his

2. Maliski SL, Heilemann MV, McCorkle R. From "death sentence" to "good cancer": couples' transformation

3. Maliski SL, Clerkin B, Litwin MS. Describing a nurse case manager intervention to empower low-income
PMID: 14722588.


5. Walling AM, Maliski S, Bogorad A, Litwin MS. Assessment of content completeness and accuracy of
prostate cancer patient education materials. Patient education and counseling. 2004;54(3):337-43. doi:


**Ongoing Research Support**

NIH/NINR 1R21NR2786A Maliski (PI) 6/11/11-5/31/13

Underserved Men's Understanding of Androgen Deprivation Therapy Related Risks

This qualitative study will develop an explanatory framework for processes used by Latino men to understand and manage androgen deprivation therapy symptoms and risks.

UCLA School of Nursing Intramural Grant Maliski (PI) 5/1/11-4/30/14

Staying Strong and Healthy

This pilot study is testing a nurse-directed telephone-based intervention to minimize the cardiovascular risks associated with androgen deprivation therapy among Latino men.

**Completed Research Support**

NIH/NINR 1R21NR010383-01A1 Maliski (PI) 9/26/08-9/25/11

Prostate Cancer Clinical Decision-Making by Diagnosed and High Risk Latino Men

This study focuses on Mexican/Mexican American men. Using qualitative methods we seek to understand prostate cancer treatment, disclosure, and screening decision processes from the perspectives of Mexican/Mexican-American men who have made prostate cancer treatment and disclosure decisions and high risk brothers and sons of Mexican/Mexican-American men who are deciding on screening.
DoD PC060612 Maliski (PI) 1/1/07-12/31/10
The Impact of Prostate Cancer Treatment-Related Symptoms on Low-Income Latino Couples.
Given the dearth of research on the effect of prostate cancer and its treatment on low-income Latino couples, the purpose of this study is to describe, using mixed qualitative and quantitative methods, the experience and impact on the relationship of prostate cancer treatment-related symptoms from the perspective of low-income Latino men and their partners.

NIH/NCI 1R03CA122896-01A1 Maliski (PI) 7/1/07-6/30/09
Health Literacy and Self-Efficacy Among Low-Income Men with Prostate Cancer.
Low self-efficacy and health literacy have been shown to impede obtaining and understanding critical health information. In this study we are examining relationships between health literacy and self-efficacy for patient-physician interaction among low-income, uninsured men being treated for prostate cancer through a state-funded program. We are also examining the relationships between health literacy, self-efficacy and quality-of-life using standardized tools.
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
Amy D. Waterman

POSITION TITLE
Associate Professor of Medicine

ERA COMMONS USER NAME (credential, e.g., agency login)
[Provided]

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

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A. Personal Statement

As a researcher and educator, I am committed that all kidney patients and potential living donors make informed transplant choices, especially ethnic/racial minorities. I am an Associate Professor of Medicine at Washington University School of Medicine (WUSM), a Health Psychologist, and the Barnes-Jewish Transplant Center Quality Manager. I have surveyed over 1000 dialysis patients, kidney recipients, and living donors of different races to understand their living donation decision-making, developed validated measures of living donor decision-making, and assessed the effectiveness of different print, video, and interactive computer educational programs to help patients consider transplant. I created the award-winning Explore Transplant videos and print materials used in over 1000 dialysis centers nationwide. I have served two years as the UNOS Living Donor Committee Vice-Chair, have published multiple papers on how best to reduce racial disparities in ESRD/ living donation.

B. Positions and Honors

8/94 – 8/99  Project Coordinator, Living Donation Research Laboratory, Department of Psychiatry, Washington University School of Medicine

3/95 – 1/01  Research Associate, Department of General Medical Sciences, Washington University School of Medicine

1/01 – 12/02 Post-Doctoral Associate, Department of General Medical Sciences, Washington University School of Medicine

1/03 – 06/04 Instructor of Medicine, Department of General Medical Sciences, Washington University School of Medicine

07/04-2011  Assistant Professor of Medicine, Department of General Medical Sciences, Washington University School of Medicine

1/2012-present  Associate Professor of Medicine, Department of General Medical Sciences, Washington University School of Medicine

Honors


2006  National Kidney Foundation Annual Meeting “Outstanding Poster” given for the following abstract, "Knowledge and Attitudinal Barriers to Transplantation for Dialysis Patients.”
2006  Society of Behavioral Medicine, Citation Abstract, given for the following abstract: “Why African-Americans Don’t Pursue Living Kidney Donation.”
2008  Telly Award, Bronze Level, Health and Wellness Category, for Explore Transplant Video Program.
2008  Explore Transplant education program chosen as an official Centers of Medicare and Medicaid Services Network Quality Initiative.
2009  American Transplant Congress, 2009, “Poster of Distinction” given for the following abstract, “Immunosuppressant Drug Costs: A Barrier To Transplant For Dialysis Patients.”
2009  Recipient of NATCO Organization of Transplant Professionals’ Quality of Care Award for Explore Transplant educational initiative.
2010  United Network of Organ Sharing Transplant Administrators’ Forum, Transplant Center Initiatives to Increase Organ Donation, 1st Place: “Training Dialysis Providers to Deliver Transplant Education.”
2012  Recipient of Skandalakis Award, YouthBridge Social Enterprise and Innovation Competition Grant awarded for Explore Transplant educational initiative.

Board Memberships
2007-2010  National Kidney Foundation of Eastern Missouri, Board Member
2008-2010  American Society of Transplantation, Organ Donation Advisory Council
2009-2012  United Network of Organ Sharing, Living Donor Committee
2009-present  Progress in Transplantation Editorial Board
2009-present  Executive Director, Explore Transplant nonprofit organization
2010-2012  National Kidney Foundation, End the Wait Committee
2010-2012  United Network of Organ Sharing, Policy Oversight Committee
2010-present  Member, American Society of Transplantation Women’s Health Community of Practice (WHCoP)

C. Selected Peer-reviewed Publications (selected from of 52 articles and 3 book chapters)


ethnic disparities in live donor kidney transplantation: priorities for research and intervention. Seminars in Nephrology, Jan;30(1), 90-98. PMID: PMC2818251.


D. Research Support

Ongoing

1D71HS19216 Waterman (PI) 09/01/10 – 08/31/13
Department of Health and Human Services, Health Resources and Services Administration
Improving Dialysis Providers’ Ability to Educate Patients about Living Donation: A Multi-State Explore Transplant Intervention
Dr. Waterman is the Principal Investigator on this grant responsible for assessing whether training dialysis providers to present Explore Transplant effectively with their own patients can significantly increase the rates of living donation in four ESRD Networks.

1 RC1 DK088711-01A1 Waterman, Amy (PI) 09/15/11-08/31/16
National Institutes of Health
Tailored Computer Education to Increase Living Donation in African-Americans
Patients with kidney failure have better health and quality-of-life when they receive a transplant, especially a transplant from a living donor (LDKT). Although kidney failure disproportionately affects African-Americans, Whites are more likely to receive LDKTs. This randomized controlled trial of 600 African-American and White patients will develop and assess the effectiveness of individually tailored, computer-generated education using an Expert System for overcoming specific barriers affecting African-Americans’ pursuit of LDKT.
D71HS22064 Waterman, Amy (PI) 09/01/11-08/31/13
Department of Health and Human Services
Health Resources and Services Administration
Training Dialysis Providers to Educate English- and Spanish-Speaking Patients about Living Donation: A National Explore Transplant Intervention
The major goal of this grant is to assess the effectiveness of e-Learning and in-person dialysis provider trainings to disseminate transplant education to 12,000 Spanish-speaking and English-speaking patients in 15 states and territories.

Completed
UL1 RR024992 Waterman (PI) 06/01/09 – 05/31/11
Institute of Clinical and Translational Sciences
Improving Kidney Transplant Education to Increase Living Donation Rates
Dr. Waterman was the Principal Investigator on this grant responsible for the design, execution, and analysis of a group-randomized controlled education trial to assess the effectiveness of an improved living donation education program for transplant patients.

1R39OT08449 Waterman (PI) 08/01/07 – 07/31/11
Department of Health and Human Services, Health Resources and Services Administration
Educating Missouri Patients about Preemptive Living Donor Transplantation: A Randomized Controlled Trial
Dr. Waterman was the Principal Investigator on this grant responsible for the design, execution, and analysis of a health education intervention to increase the rates of preemptive transplant for kidney disease patients before they begin dialysis.

1R01 DK079665 Rodrigue (PI) 03/01/09 – 06/30/12
NIH/National Institute of Diabetes, Digestive, and Kidney Disease
A Randomized Trial to Reduce the Disparity in Live Donor Kidney Transplantation
Dr. Waterman is a Co-Investigator on this grant responsible for the design and assessment of a living donation education program focusing on reducing health disparities in pursuit of transplant.

R39OT10582 Waterman (PI) 09/01/08 – 08/31/12
Department of Health and Human Services, Health Resources and Services Administration
Training Dialysis Providers to Promote Living Donation: A Four-State Explore Transplant Intervention
Dr. Waterman is the Principal Investigator on this grant responsible for assessing whether training dialysis providers to present Explore Transplant effectively with their own patients can significantly increase the rates of living donation in four states.
1. Project Director / Principal Investigator (PD/PI)

Prefix: Dr. 
* First Name: Jeffrey 
Middle Name: 
* Last Name: Veale 
Suffix: MD

2. Human Subjects

Clinical Trial? ✗ No ☐ Yes

* Agency-Defined Phase III Clinical Trial? ☐ No ☐ Yes

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: Ms. 
* First Name: Kim 
Middle Name: 
* Last Name: Duiker 
Suffix: 

* Phone Number: 310-794-0155 Fax Number: 310-943-1658

Email: ocga58research.ucla.edu

* Title: Assistant Director

* Street 1: 11000 Kinross Avenue, Suite 211
Street2: 
* City: Los Angeles
County/Parish: Los Angeles County
* State: CA. California
Province: 
* Country: USA. UNITED STATES * Zip / Postal Code: 90095-1406
4. 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://stemcells.nih.gov/research/registry/. 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.
## PHS 398 Modular Budget

### Budget Period: 1

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Cognizant Agency (Agency Name, POC Name and Phone Number)  
DHHS, Wallace Chan, 415-437-7820

Indirect Cost Rate Agreement Date 04/27/2011

Total Indirect Costs 81,000.00

#### C. Total Direct and Indirect Costs (A + B)

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Cognizant Agency (Agency Name, POC Name and Phone Number)  
DHHS, Wallace Chan, 415-437-7820

Indirect Cost Rate Agreement Date 04/27/2011

Total Indirect Costs 67,500.00

#### C. Total Direct and Indirect Costs (A + B)

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# PHS 398 Modular Budget

## Cumulative Budget Information

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## 2. Budget Justifications

- ? Personnel Justification
  - Personnel_Justification1024834
  - [Add Attachment](#)
  - [Delete Attachment](#)
  - [View Attachment](#)

- ? Consortium Justification
  - [Add Attachment](#)
  - [Delete Attachment](#)
  - [View Attachment](#)

- ? Additional Narrative Justification
  - [Add Attachment](#)
  - [Delete Attachment](#)
  - [View Attachment](#)
UCLA BUDGET JUSTIFICATION

PERSONNEL

Jeffrey Veale, MD, Co-Principal Investigator (calendar months). Dr. Veale will serve as Co-Principal Investigator for the proposed study. He is the Director of UCLA Donor Exchange Program (UDEP) and Associate Professor at the Department of Urology. He is also the Surgical Director of the National Kidney Registry and Chair of the Registry's Surgical Committee. Dr. Veale is a true pioneer of exchange transplantation, performing the first chain transplantation in the Western United States, the first transplantation of an altruistic donor kidney that was shipped on a commercial airline in the United States, and the first Asynchronous, out-of-sequence, transcontinental chain kidney transplantation in the world. His groundbreaking work in shipping living donor kidneys unaccompanied on commercial airlines has revolutionized the field. Previously a donor participating in an exchange would be required to travel to an unfamiliar city where the exchange recipient was located. Now in the majority of exchanges the kidney rather than the donor travels to the recipient's hospital on a commercial airline. This allows the donor to recover with their loved one (intended recipient), among family and friends. This has dramatically decreased costs and enables donors to recover in their familiar surroundings.

Study Responsibilities:
Dr. Veale will serve as Co-Principal Investigator for the proposed study and will work closely with the Co-Principal Investigator, Dr. Sally Maliski, recruitment sites and staff. In this role, he will:
  - Oversee all research efforts
  - Meet with the research staff regularly to monitor progress
  - Assist in the recruitment of study participants by leveraging his existing clinical relationships
  - Participate in the Advisory Committee
  - Assist in the design and implementation of the study
  - Lead the instrument development aspect of the proposal
  - Data analyses
  - Ensure that all the specific aims are completed
  - Be responsible for fiscal management of the project
  - Be responsible for all agency reporting requirements
  - Manuscript preparation

Sally L. Maliski, PhD, RN, Co-Principal Investigator (calendar months). Dr. Maliski will serve as Co-Principal Investigator for this study along with Dr. Veale. Dr. Maliski is an Assistant Professor and the Associate Dean of Academic Affairs at the School of Nursing at UCLA, has conducted research with underserved males from clinical populations over the past ten years. Dr. Maliski and her team are experienced with the use of grounded theory and the conduct of qualitative studies including individual interviewing. Dr. Maliski's research accolades have led her to receive one of nursing's highest honors “Fellow of the American Academy of Nursing”.

Study Responsibilities:
Dr. Maliski will serve as Co-Principal Investigator for the proposed study and will work closely with Dr. Veale, recruitment sites and staff. In this role, she will:
  - Oversee all qualitative research efforts
  - Meet with the research staff regularly to monitor progress
  - Participate in the Advisory Committee
  - Assist in the design and implementation of the study
  - Ensure that all the specific aims are completed
  - Data analyses
  - Manuscript preparation
OTHER PERSONNEL - RESEARCH SUPPORT.

Elisabeth Hicks, MA, Study Coordinator. Ms. Hicks, a staff member of the UCLA Urology Research Core (UURC). Ms. Hicks is a qualitative researcher with several years working in research coordination at the University of British Columbia and the University of Southern California. With a MA in Cultural Geography she is well versed in critical theory in the social sciences. She offers expertise in the design, implementation, and analysis of qualitative studies. She has also worked in clinical settings and with diverse participant groups. Ms. Hicks is currently the study coordinator for Drs. Veale and Maliski’s pilot study.

Study Responsibilities: Ms. Hicks will serve as study coordinator for the proposed study and will work closely with Drs. Veale and Maliski and the research team. In this role, she will:
- Oversee and coordinate the day-to-day operations of the study.
- The development and maintenance of study database.
- Recruit and consent participants.
- Manage participant incentives.
- Prepare and send all necessary information to research participants (e.g., confirmation letters, appointment reminders, study information).
- Conduct qualitative interviews.
- IRB submissions at each site.

Total salary requested will be paid from the UURC via a sales and service agreement.

Lorna Kwan-Herbert, MPH, Senior Statistician. Ms. Kwan is a member of the UCLA Urology Research Core (UURC) and has an extensive background in data management and statistical analysis across several platforms, including Microsoft Access and SAS 9.0. Ms. Kwan has created and maintained large databases (100,000+ observations) to manage the data collection, entry, and validation for several quality of life research studies as well as conducting multivariate analyses for these studies including repeated measures, survival analysis, logistic regression, and mixed modeling. Ms. Kwan has conducted the analyses for multiple studies over the past 8 years working closely with Drs. Veale and Maliski and their research team.

Study Responsibilities: Ms. Kwan will:
- Assist Drs. Veale and Maliski with statistical analysis and evaluation of the project.
- Assist in the preparation of manuscripts and abstracts for submission.

Total salary requested will be paid from the UURC via a sales and service agreement.

CONSULTANT

Amy D. Waterman, PhD, Consultant. Dr. Waterman is an Associate Professor of Medicine at Washington University School of Medicine (WUSM), a Health Psychologist, and the Barnes-Jewish Transplant Center Quality Manager. She has surveyed over 1000 dialysis patients, kidney recipients, and living donors of different races to understand their living donation decision-making, developed validated measures of living donor decision-making, and assessed the effectiveness of different print, video, and interactive computer educational programs to help patients consider transplant. Dr. Waterman created the award-winning Explore Transplant videos and print materials used in over 1000 dialysis centers nationwide. She has served two years as the UNOS Living Donor Committee Vice-Chair, have published multiple papers on how best to reduce racial disparities in ESRD/living donation, and an R01-funded researcher. In this role, she will:
- Advise the planning, execution, and analysis of this project.
- Provide expertise on measurement and educational development.
- Attend Advisory Committee meetings by teleconference.
- Review all study and educational materials.
# PHS 398 Research Plan

## 1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

- **Type of Application:**
  - [ ] New
  - [x] Resubmission
  - [ ] Renewal
  - [ ] Continuation
  - [ ] Revision

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. **Introduction to Application**
   - Introduction_to_Application
     - [Add Attachment] [Delete Attachment] [View Attachment]

   *(for RESUBMISSION or REVISION only)*

2. **Specific Aims**
   - Specific_Aims1024836152.pdf
     - [Add Attachment] [Delete Attachment] [View Attachment]

3. **Research Strategy**
   - Research_Plan_2013_7_161024
     - [Add Attachment] [Delete Attachment] [View Attachment]

4. **Inclusion Enrollment Report**
   - [Add Attachment] [Delete Attachment] [View Attachment]

5. **Progress Report Publication List**
   - [Add Attachment] [Delete Attachment] [View Attachment]

### Human Subjects Sections

6. **Protection of Human Subjects**
   - Human_Subjects1024836154.pdf
     - [Add Attachment] [Delete Attachment] [View Attachment]

7. **Inclusion of Women and Minorities**
   - Inclusion_of_Women_and_Minorities
     - [Add Attachment] [Delete Attachment] [View Attachment]

8. **Targeted/Planned Enrollment Table**
   - Enrollment_Table1024836156.
     - [Add Attachment] [Delete Attachment] [View Attachment]

9. **Inclusion of Children**
   - Inclusion_of_Children102483
     - [Add Attachment] [Delete Attachment] [View Attachment]

### Other Research Plan Sections

10. **Vertebrate Animals**
    - [Add Attachment] [Delete Attachment] [View Attachment]

11. **Select Agent Research**
    - [Add Attachment] [Delete Attachment] [View Attachment]

12. **Multiple PD/PI Leadership Plan**
    - Multiple_Pi_Plan1024836158.pdf
      - [Add Attachment] [Delete Attachment] [View Attachment]

13. **Consortium/Contractual Arrangements**
    - [Add Attachment] [Delete Attachment] [View Attachment]

14. **Letters of Support**
    - Letters_of_Support102483615
      - [Add Attachment] [Delete Attachment] [View Attachment]

15. **Resource Sharing Plan(s)**
    - Resource_Sharing_Plan102483
      - [Add Attachment] [Delete Attachment] [View Attachment]

16. **Appendix**
    - [Add Attachments] [Remove Attachments] [View Attachments]
Specific Aims

Kidney transplants are life saving for those with end-stage renal disease (ESRD), providing the possibility of a relatively healthy and productive life. The five-year survival rate for ESRD patients on dialysis is only 35%, while the rate for those receiving kidney transplants is 72% [1]. Unfortunately, the supply of donor kidneys does not meet the enormous demand. There are over 600,000 individuals living on dialysis and over 96,650 candidates waiting on deceased kidney donor lists in the United States [2, 3]. Living donor kidneys provide significantly superior outcomes compared to organs from deceased donors, but only about a third of transplants in recent years came from living donors [2, 4-7]. Approximately 35% of candidates who have a willing living donor have traditionally been unable to receive a kidney from that intended donor due to crossmatch or blood type incompatibility [8, 9]. This group represents a large pool of willing potential donors that remains untapped.

Transplant chains triggered by non-directed (altruistic) donors are a novel approach to this problem that capitalizes on the generosity of these incompatible donors. Chains are initiated when a non-directed donor donates a kidney to a recipient who has a willing but incompatible donor. Once this recipient is transplanted, his or her original incompatible donor then passes on the generosity to another recipient. Once the second recipient receives a transplant, her original incompatible donor likewise passes on the generosity to a third recipient. This process can be repeated for multiple iterations, creating long chains of transplantations involving upwards of 30 recipients and utilizing willing donors who may otherwise have been unable to donate, thus increasing the living donor pool and expanding the potential benefit from each individual non-directed donor [10-12].

Two types of living donors are essential to the creation of transplant chains: non-directed donors and bridge donors. Non-directed donors have no intended recipient and plan to donate to a stranger. Bridge donors originally intended to donate a kidney to family/friend, but were determined to be incompatible with their intended family/friend. Thus, bridge donors donate to a stranger as part of a chain instead. The patients who receive transplants as part of chains are removed from the deceased donor waiting list, enabling other candidates to move up the waiting list and take their spots. This approach has potential to increase the number of living donors, decrease the competition for deceased donor organs, and ease the strain on the waiting list, yet very little is known about how non-directed donors and bridge donors make decisions about donating a kidney, nor about characteristics of potential donors who actually donate versus those who do not complete the donation process.

Therefore, we will use a mixed-methods, cross-sectional approach informed by a committee of stakeholders to describe characteristics of and decisional processes used by potential bridge donors and non-directed donors who complete the donation process and those who do not. We will leverage our center's unique position as one of the largest in the nation [13], the National Kidney Registry's (NKR) position as the largest facilitator of chains in the world, and Living Donation California's (LDC) status as the first living donor registry to carry out this groundbreaking work. Specifically, we aim to:

1. Elicit in-depth narratives from actual and non-completing bridge donors and non-directed donors about their experience of the donation process.
2. Describe socio-demographic (age, gender, occupation, education, income, insurance status, relationship status), cultural (ethnicity, acculturation, religion), physical (co-morbidities), and psychological (health-related quality of life (HRQOL), depression, anxiety) characteristics of actual and non-completing bridge donors and non-directed donors.
3. Develop an explanatory framework of decisional processes used by potential and actual bridge donors and non-directed donors including factors and characteristics that influence decisions.

Results from this study will be the first to provide an in-depth description of potential and actual non-directed and bridge kidney donors, which will provide the foundation upon which to develop educational materials for individuals contemplating kidney donation, strategies through which to recruit potential non-directed and bridge donors, tools to identify and address potential breaking points in chains, and hypotheses to further explore these new and innovative phenomena. The novel characterization of non-completing donors in particular will offer unique insight into expanding the promising strategy of chain transplantation while protecting both the rights of those who choose not to donate and the interests of those in need. The framework developed in this study is critical to the development of screening, education, and decision making tools for our collaborators, NKR and LDC, to use in their everyday operations. Upon the completion of this study, we plan to collaborate with NKR, LDC, and our consultant Dr. Amy Waterman to develop tools such as those described above.
Significance
End-stage renal disease (ESRD) is an immense public health problem. Medicare expenditures for ESRD are over $33 billion. There are currently over 96,000 people on the waiting list for a kidney transplant; only 16,485 received a transplant in 2012, and only 5,617 of those were from living donors [2]. The low rate of living kidney donations is especially significant considering that living donor kidneys function nearly twice as long as kidneys from deceased donors, that those who receive transplants have more than twice the 5-year survival rate as those on dialysis, and that per person per year Medicare expenditures for hemodialysis patients are nearly $90,000 – almost three times the per person per year expenditures for transplant patients [3-7]. Worse, the demand for organs will likely only increase in the coming years as obesity, which leads to diabetes – the leading cause of renal failure – takes its toll on the American public, 39.5% of whom were obese or extremely obese as of 2008 [14]. Increasing demand will only make it more difficult for those tens of thousands of patients desperately hoping for a transplant from a stagnant supply.

Transplant chains offer a unique solution to the enormous gap between supply and demand, offering the potential for one non-directed donor to help more than one recipient [10, 12, 13, 15-18]. In the past, a non-directed donor would donate to a single individual on the waiting list, but with the establishment of chains in 2009, a single altruistic donor can trigger upwards of 30 transplants [10, 11, 17]. Additionally, the recipients who receive a living donor kidney as part of a chain are removed from the deceased donor waiting list, enabling other candidates to move up. Reducing competition on the waiting list is essential when considering the 4,366 people who died waiting for a deceased donor kidney transplant in the US in 2012 [2], to say nothing of the thousands who continue waiting on dialysis at a per person, per year cost that averaged $87,561 in 2010 [3].

Chains have their roots in traditional kidney paired donation, or swaps. As depicted in Figure 1, a donor (Donor A) who is incompatible with the intended recipient (Recipient A) instead donates to another recipient (Recipient B). In turn, that recipient’s (Recipient B) intended but incompatible donor (Donor B) donates back to the first recipient (Recipient A). This system allows patients with willing but incompatible donors to exchange for compatible donor kidneys. The inception of altruistic donor chains by Dr. Michael Rees in 2009, however, revolutionized the field by extending this formula to exchange kidneys between long chains of incompatible pairs in a domino fashion [17]. With evidence supporting the safety and feasibility of transporting live donor kidneys across large distances on commercial airlines, the promise of nationwide chains has become realizable [15, 19, 20]. The National Kidney Registry (NKR), the leading multicenter kidney exchange network, has facilitated over 750 transplantations between various centers across the United States, suggesting great potential for expansion [21].

There are two subtypes of donors within these chains who will be the focus of our research study. Non-directed donors are individuals who donate a kidney but are not motivated by an incompatible recipient. Bridge donors, on the other hand, were initially willing to donate to a friend or family member, but are incompatible with their intended recipient. Once the bridge donor’s friend or family member receives a kidney, they pass on the generosity by donating a kidney to a stranger as part of a chain of transplantations (Figure 2).

![Figure 1. Kidney Paired Donation](image1.png)

![Figure 2. Kidney Transplant Chain](image2.png)

Results of the few studies conducted with altruistic donors (including both non-directed and bridge donors) indicate that they do not significantly differ in outcomes from traditional donors who have a prior relationship with their recipients. In one study using self-report questionnaires, 39 altruistic donors did not significantly differ from 52 traditional donors relative to their motivations for donating, the interpersonal and emotional benefits they received from donating, or their physical functioning after donation, and the majority of both types of donors reported that they would make the decision to donate again [22]. Donors in this sample were predominantly female and White non-Hispanic, had generally completed at least a college degree, had insurance, and had a household income greater than $50,000/year. In interviews with 24 altruistic donors,
donors reported very high satisfaction with donation, that donation positively impacted their lives, and very little negative impact on their physical well-being [23]. These participants were also predominantly married, but were somewhat more diverse in terms of gender and education. Unfortunately, nearly all participants in these studies were non-directed donors, while the experiences of bridge donors have been largely overlooked.

Although guidelines have been developed for the psychosocial evaluation of altruistic donors in order to minimize concerns about coercion, informed consent, and poor psychosocial outcomes, these concerns continue to be a topic of debate [22, 24-27]. Guidelines for screening live donors vary greatly across transplant programs [28, 29]. The field lacks consistent and effective guidelines to help screen potential altruistic donors [22, 30]. Thus, it is essential to fully understand the decision making processes involved in becoming an altruistic donor, the factors that predict which potential donors will actually go on to donate, and the characteristics of donors who have negative outcomes following their donation. It is particularly important to differentiate between non-directed donors and bridge donors in this investigation, as the presence of an incompatible loved one may make the process substantially different for bridge donors.

Results from this study will be the first to provide an in-depth description of potential and actual non-directed and bridge kidney donors, which will provide the foundation upon which to develop educational materials for individuals contemplating kidney donation, strategies through which to recruit potential non-directed and bridge donors, tools to identify and address potential breaking points in chains, and hypotheses to further explore these new and innovative phenomena. The novel characterization of non-completing donors in particular will offer unique insight into expanding the promising strategy of chain transplantation while protecting both the rights of those who choose not to donate and the interests of those in need. The framework developed in this study is critical to the development of screening, education, and decision making tools for our collaborators, NKR and LDC, to use in their everyday operations. Upon the completion of this study, we plan to collaborate with NKR, LDC, and our consultant Dr. Amy Waterman to develop tools such as those described above.
**Innovation.** This study is innovative in its examination of altruistic kidney donors through a mixed-methods approach. There is a dearth of research on the qualitative experiences of altruistic kidney and bridge donors participating in chains. To our knowledge, no other studies have investigated the decisional experience of both potential donors who do not go on to donate and actual donors. No explanatory framework has yet been developed for the decisional process of altruistic donors participating in chains, and this lack of knowledge has inhibited the development of effective recruitment strategies.

Additionally, no previous study has investigated the differential experiences of non-directed donors and bridge donors. Given their different positions at the beginning and in the middle of kidney donation chains as well as their different relationships to the recipients in the chains, it can reasonably be expected that the decisional processes of whether to donate and the experiences of actually donating are substantially different for non-directed and bridge donors. In order to best understand their experiences and thus appropriately inform the development of strategies, interventions, and educational materials to recruit altruistic donors and improve their donation experiences, it is essential to understand how the experiences of non-directed donors and bridge donors differ.

Finally, the melding of the expertise of the Principal Investigators provides a unique aspect to the study. Dr. Veale, though his academic career is in its early stages, has extensive experience in transplantation, a vast network of connections in the kidney transplant community, including many former patients, and expertise in the kidney transplantation policy. Dr. Veale is the Director of the UCLA Donor Exchange Program (UDEP), and the Surgical Director of the National Kidney Registry (NKR), the largest and most successful exchange registry in the world. He also chairs the NKR Surgical Committee and is an advisor to Living Donation California (LDC), the first ever registry of altruistic donors. Dr. Malinski, meanwhile, has developed expertise in the conduct of qualitative-dominant mixed-methods research with clinical populations. She has vast experience in developing, conducting, and analyzing qualitative interviews, as well as excellent relationships with trained qualitative interviewers, qualitative research experts, and an experienced research team. The combination of the skills and resources of the Principal Investigators will provide a solid foundation and a unique approach to this study.

**Approach. Design.** We will use a descriptive, qualitative-dominant, mixed-methods design incorporating concurrent qualitative and quantitative data collection and analysis techniques consistent with constructivist grounded theory—and drawing from symbolic interactionism [31-33]. We chose a qualitative-dominant design because qualitative methods are best suited to areas about which little is known. The quantitative methods will play a supportive, but important role in this study. By employing this type of mixed-methods design we will achieve complementarity (the examination of overlap and different facets of phenomena), initiation (the discovery of fresh perspectives), and expansion (addition of breadth and scope to a project), all of which are essential to grounding the development of recruitment and screening strategies which are sensitive to the experiences of bridge donors and non-directed donors [34]. The quantitative measures chosen will be consistent with a symbolic interaction framework and will work in concert with the qualitative data. Analyses will be for enhanced description rather than statistical significance. For example, should a number of bridge donors describe an experience significantly differently than the rest of the bridge donors, we will examine the quantitative data to see if certain characteristics may differentiate this group from other bridge donors.

**Recruitment.** We will recruit 30 potential bridge donors and 30 potential non-directed donors who did not go on to donate as well as 30 actual bridge donors and 30 actual non-directed donors. This is more than sufficient for grounded theory analysis for which 20-30 in-depth interviews are recommended to achieve category saturation [35]. We are not powering the sample to detect statistical significance for the quantitative measures because they will function secondarily to the qualitative analysis, providing one means of categorization of the participants and one component of the description of participants’ experiences to be developed in this study.

We will recruit men and women who have donated altruistically through NKR, LDC, and the UCLA Kidney Transplant Program (UKETP) or who have contacted these programs with an interest in donating altruistically but did not eventually go on to donate. Patients must be 21 years or older and able to read and speak English, as the experience of non-English speaking donors is likely to be substantially different and will be the subject of a planned subsequent study. Potential participants who are eligible will be recruited for this study regardless of their gender or minority status. Based on the experience of Dr. Veale, the relevant population consists of about 47% women and 48% people of a minority race/ethnicity. Minorities consist of approximately 19% African Americans, 14% Latinos, 10% Asians, and 5% other races/ethnicities. Because minorities are historically underrepresented in the kidney transplant population, we will oversample minorities and constantly monitor sample demographics to target small cell sizes.
After IRB approval, we will compile a database of eligible individuals from the NKR, LDC, and UKTP. We will stratify by race, ethnicity, and sex, and then randomly select individuals to be contacted. This will be accomplished through random number generation by the team’s statistician. The study coordinator will mail a letter describing the study and inviting participation. The study coordinator will follow up within 2 weeks by phone. Potential participants will have the opportunity to ask any questions about the study. If they are interested, the study coordinator will mail an informed consent document to the participant along with an addressed, stamped envelope for return. If the signed consent document is not received within 2 weeks of mailing, the study coordinator will call to follow up and confirm interest in participation. If the study coordinator is unable to contact the participant for a further two weeks, the potential participant will be considered lost.

We do not expect difficulty attaining recruitment goals. In pilot work with similar populations, participants were extremely responsive. Additionally, the UKTP is one of the largest transplant programs in the country, completing over 300 transplants a year. In its history, it has completed over 6,000 kidney transplants. We believe LDC will be a rich source of potential donors, particularly given the media attention it has received and its promising level of web traffic. In the first month the site received 1,985 visits. Subsequently, 4 potential donors were identified and 3 were referred to transplant centers. LDC was created in 2010 by the California State Legislature and is the first living donor registry in the world. Dr. Veale and members of our Advisory Committee (Mr. Mone and Mr. Stewart, see letters of support) are involved in the project in various capacities. The NKR database contains data on over 750 transplants representing approximately 150 chains from across the United States. It includes patient characteristics of waitlisted donors waiting for a matched recipient. As of June 2012, there were 314 active waitlisted donors.

Data Collection. After written consent is received, the study coordinator will contact each participant to schedule an interview and obtain demographic information, which will include sex, age, race, ethnicity, education level, income, marital status, type of donation considered, time since donation decision, and time since donation, if applicable (See Appendix A). The study coordinator will call the participant the day before the interview as a reminder, or on the closest working weekday in the case of weekends and holidays. Interviews will be conducted by telephone to avoid prohibitive travel costs, as donors will likely be spread across large geographic distances.

There are a number of limitations in conducting qualitative interviews by telephone. The interviewers will not be able to see body language, facial expressions, or the environment. We will have to rely on tone of voice for nonverbal communication. Despite these limitations, we have found in previous studies that telephone interviewing has provided the depth of information needed for qualitative analysis and allows access to those individuals who do not wish to travel or to have an interviewer in their home [36, 37]. The telephone is convenient for the participant, thereby reducing their participation burden and enhancing retention.

Project interviewers have been or will be trained in qualitative interviewing techniques and will be supervised by Dr. Malinski, who is experienced in qualitative interviewing. Participants will be apprised that their participation is voluntary, they have the right not to answer questions they wish not to discuss with no penalty to them, and that interviewers will be sensitive to fatigue or discomfort. All participant identifiers will be removed from transcripts during transcription and all data will be secured in locked or password-protected files. Participants will receive a $15 gift card for their time once they have completed their interviews.

The semi-structured interview guide will be developed with input from the advisory committee, which will be composed of stakeholders from the kidney transplant community, including past donors and recipients, family members of past donors and recipients and administrators from donation organizations (See letters of support). A sample interview guide used by Dr. Veale in a previous study is included in Appendix B. In addition to areas of interest identified by the advisory committee, the interview will focus on the factors that initially interested participants in donation, their experience of their decisions to donate or not to donate, and the effects their decisions had on their lives. Interviews are expected to last 1-1.5 hours. All interviews will be digitally recorded and transcribed verbatim. Data collection will continue until all categories are completed with fully described properties and dimensions. We will conduct follow-up interviews with 10 participants from each cohort, selected by randomization, to confirm and expand upon categories. These participants will receive a second $15 gift card.

The advisory committee will also advise the selection of the quantitative measures. These measures will give us a brief snapshot of our participants' well-being, which may in turn assist in our interpretation of their interview responses as described above. They will include, at minimum, a measure of HRQOL, a measure of depression, and a measure of anxiety. Measures will be administered orally by the interviewers at the beginning of the interview and answers will be recorded. Suggested measures are as follows: (1) The SF-36 is
a widely used generic measure of HRQOL divided into 8 subscales that fall under either physical or mental health[38]. It is comprised of 36 individual items and can be completed in 5-10 minutes. It has proven to be valid and reliable in many populations [38, 39]. It is also the most widely used HRQOL measure in kidney donor and recipient populations, allowing for comparison of results across studies [40]. (2) The Beck Depression Inventory (BDI) is the most widely used depression measure in the kidney transplant literature, and has been consistently used in the donor and recipient populations since the 1980s[40]. It has been found to be valid, reliable in both clinical and nonclinical populations [41]. It consists of 21 items and takes 5-10 minutes to complete. A meta-analysis found the BDI to have an average internal consistency of .85 in adults [42]. A separate meta-analysis found it to have high content and discriminant validity, as well as high sensitivity to change[43]. (3) The Beck Anxiety Inventory similarly consists of 21 items. It has been found reliable and valid in clinical and nonclinical samples [44-46], and has also been used to evaluate anxiety in kidney donor and recipient populations [47, 48]. Internal consistency is high (.94), as are convergent and discriminant validity[44].

Advisory Committee. The advisory committee for this study will consist of eight stakeholders, four men and four women, all of whom have worked with Dr. Veale in the past (See letters of support). Kidney donation advocates, kidney recipients, kidney donors, family members of kidney donation recipients, and donation organization administrators will all be represented. The advisory committee will be called upon to refine draft versions of the semi-structured interview guides and in the selection of quantitative measures to be used in the study, to review and provide feedback on data obtained, and to assist with dissemination of study results. Meetings will be held quarterly and as needed by teleconference. Discussions will also occur electronically and by teleconference in smaller groups depending on the topic and recommendations of the advisory committee.

Analysis. All responses to quantitative instruments will be transferred into an SAS (Cary, NC) database for descriptive analyses. All qualitative interviews will be digitally recorded and transcribed verbatim. Qualitative and quantitative analyses will be conducted concurrently with results from each informing the other. Analysis will also be concurrent with data collection. Because this dominant qualitative mixed-methods study is not powered to detect statistically significant differences, qualitative data and analysis results will be combined with qualitative results to strengthen the description of the experience of a donation decision on participants. The scores for each participant can be combined with the themes emerging from their qualitative data to form a more complete description. For example, some subgroups may describe certain experiences in similar ways, and responses to quantitative items may further differentiate these groups. The qualities described in these quantitative items may then assist us in typifying these subgroups for further investigation. We may also see experiences not suggested in interviews – such as experiences of depression – in quantitative data, which we would then further probe in subsequent interviews. It is not our intent to make statistical inferences from these data.

Qualitative analysis will be conducted according to constructivist grounded theory technique as described by Charmaz [33]. Each transcript will be read in its entirety by the Principal Investigators. Initial, close line-by-line coding using gerunds will be conducted by Dr. Maliski and trained study staff. Transcripts and initial coding will be entered into ATLAS.ti v.7 to manage data as early codes are clustered into categories. Axial coding will then be conducted during which each category will be fully described, returning to codes and using theoretical sampling to expand areas that are not completely described and developed into concepts. Finally, relationships among concepts will be identified which will lead to articulation of a model of donor decision-making grounded in the narratives of the participants.

All concepts and categories will be verified by the Principal Investigators, with Dr. Maliski leading analysis and Dr. Veale providing context and interpretation from the field at large. Participants’ responses to the instruments will be integrated into the overall analysis to provide a broader picture of participants’ experiences. To examine the qualitative data from another perspective, we will categorize participants as high or low HRQOL and mental health based on median scores in this group. We will then investigate concepts from the qualitative analysis based on this grouping and evaluate whether this distinction has significance.

Quality and rigor will be maintained throughout study. All interviewers will be trained and supervised by Dr. Maliski, who will conduct a training session with each interviewer covering the purpose of the study, qualitative interview techniques, strategies and policies for dealing with any clinical concerns that may arise with regard to the mental health of the participant, the interview guides for this study, digital recording, and importance of debriefing by completing field notes. Interviewers will conduct and digitally record a practice interview. Drs. Maliski and Veale will review the recorded interview and provide comments to the interviewer. Interviewers will complete a debriefing form after each interview that asks them to describe the tone of voice, background noise, and their feelings about the interview and assessment of their interview skills. Dr. Maliski will review transcripts...
for depth of interview techniques and provide comments during weekly contact with the interviewers. All transcripts will be compared to the taped interviews for accuracy by the study coordinator. During the analysis process, Drs. Maliski and Veale will confirm resonance of the interpretation with participants and maintain a complete analysis log that details analysis decisions, processes, and interpretations such that an audit trail for the results is available. If methodological questions arise, Dr. Maliski has a network of qualitative research experts at UCLA who are available to provide informal consultation.

Consistent with the tenets of grounded theory research, the outcome of the study will be a descriptive theory grounded in the data provided by each participant in the study [49]. This will then form a foundation for the development of sensitive strategies and materials to recruit bridge and non-directed donors, screen potential donors, and to identify and address potential breaking points in transplant chains.

Preliminary Research by the Principal Investigators
Sally L. Maliski, PhD, RN (Principal Investigator), an Associate Professor and the Associate Dean of Academic Affairs at the School of Nursing at UCLA, has conducted extensive research with underserved men and women from clinical populations. Dr. Maliski and her team are experienced with the use of grounded theory and the conduct of qualitative studies. Dr. Maliski’s research accolades have earned her one of nursing’s highest honors “Fellow of the American Academy of Nursing”. A selection of examples from her work follows.

The impact of prostate cancer treatment-related symptoms on low income racial and ethnic minority men and their families. Analysis of in-depth qualitative interviews of low-income racial and ethnic minority men found that men go through a process of renegotiating masculine identity such that they continue to have a sense of being a man [50-52]. Currently, Dr. Maliski is conducting a mixed-methods study to describe the impact of prostate cancer treatment-related symptoms on Latino families, including how couples cope and how men in the family understand hereditary risk when a member of the family is affected by prostate cancer.

Symptoms and Outcomes Related to Prostate Cancer Treatment. Fatigue following prostate cancer treatment was associated with significantly worse scores in general and disease-specific HRQOL domains when entering treatment. Men experiencing fatigue were more likely to have received treatment in a public facility than a private one [53]. Dr. Maliski is also exploring the clustering of prostate cancer treatment-related symptoms, finding that among insured males treated in a private facility about a third (33%) reported experiencing 3 or more co-occurring symptoms 8 months after treatment [54]. Poor emotional well-being and poor energy figured prominently in all symptom clusters. Additionally, when low-income males were on a waiting list to receive state-subsidized services during a state enrollment suspension, their HRQOL scores were worse and did not recover to the same degree as those who received state-subsidized services with nurse case management [55].

Jeffrey L. Veale, MD (Principal Investigator), is the Director of UDEP and Associate Professor at the Department of Urology. He is a true pioneer of exchange transplantation, performing the first chain transplantation in the western United States and the first asynchronous, out-of-sequence, transcontinental chain kidney transplantation [15, 20]. His groundbreaking practice of shipping living donor kidneys on commercial airlines, while initially controversial, is now a standard practice in chains.

Dr. Veale’s cutting edge work was recently featured in the New York Times when he performed 7 of the 30 transplants in the longest chain in history [56]. He also recently published in the New England Journal of Medicine on the potential of expanding exchanges internationally [56]. Dr. Veale has been instrumental in developing the logistical and financial policies critical to the success of exchanges, and currently serves on the Advisory Board of the LDC. This registry has grown from a 2010 vision of Steve Jobs, co-founder and former chairman and chief executive officer of Apple Inc., and former Governor Arnold Schwarzenegger to help develop and promote altruistic donation, and launched in May 2013 [57, 58]. Dr. Veale has an extensive network of contacts within the transplantation community, and plans to utilize this network to ensure the success of the study.

Amy Waterman, PhD (Consultant) is a social psychologist at the Washington University in St. Louis Medical School and the founder of Explore Transplant, a non-profit organization aimed at delivering education and decision making tools to ESRD patients. Dr. Waterman conducts research exploring the decision making of such patients and the barriers to obtaining a transplant they face. She also works to develop educational materials to assist them in their decision making processes. Her work has been funded through the R01 and K01 mechanisms, and has produced more than 50 peer-reviewed research articles. Much of this work has targeted outreach and education efforts toward racial minority populations, giving Dr. Waterman a perspective which will be helpful in the recruitment efforts of this study.
PROTECTION OF HUMAN SUBJECTS

A. Human Subjects Involvement, Characteristics, and Design

Number of Participants

Group 1: 30 people who considered becoming a non-directed donor but did not complete a kidney donation and 30 people who considered becoming a bridge donor but did not complete a kidney donation

Group 2: 30 actual non-directed donors and 30 actual bridge donors

Inclusion Criteria

Group 1
- 21 years of age or older
- Able to read and speak English
- Chose not to donate a kidney after considering becoming a non-directed donor or a bridge donor

Group 2
- 21 years of age or older
- Able to read and speak English
- Donated a kidney as either an non-directed donor or a bridge donor

Exclusion Criteria

Exclusion criteria for both groups are the same. Patients unable to read or speak English will be excluded from the current study, as the experience of non-English speaking donors is likely to be substantially different and will be the subject of a planned subsequent study. Those who have not considered becoming a non-directed donor or bridge donor will also be excluded.

Subject Recruitment

After IRB approval, we will compile a database of eligible individuals from the National Kidney Registry (NKR), Living Donation California (LDC), and the UCLA Kidney Transplant Program (UKTP). We will stratify by race, ethnicity, and sex, then randomly select individuals to be contacted using random number generation. The study coordinator will mail these individuals letters describing the study and inviting their participation. The study coordinator will follow up within two weeks by phone. Potential participants will have the opportunity to ask questions about the study. If they are interested, the study coordinator will mail an informed consent document of the participant along with an addressed, stamped envelope for return. The document will also include the study coordinator’s contact information if participants have further questions upon receipt of the document. If the signed consent document is not received within 2 weeks of mailing, the study coordinator will call to follow up and confirm interest in participation. If the study coordinator is unable to contact the participant for a further two weeks, the potential participant will be considered lost.

Length of Subject Participation

Participation in this study consists of one telephone interview with oral administration of quantitative instruments, which is expected to take 1-1.5 hours to complete. For 10 participants from each of the 4 groups of 30, it will also include a follow-up interview, which is expected to take approximately 1 hour to complete. Participants will receive a gift card for each interview they complete.

Study Design

We will use qualitative-dominant, mixed methods, cross-sectional design.

Participants for this study will be recruited from NKR, LDC, and the UKTP as described above.

After written consent is received, the study coordinator will contact each participant and answer any further questions, obtain verbal consent, obtain demographic information, and schedule the interview. Demographic information will include sex, age, race/ethnicity, education level, income, marital status, type of donation considered, time since donation decision, and time since donation (if applicable). The study coordinator will
conduct a reminder/confirmation call the day before the scheduled interview, or on the closest business day in the case of weekends and holidays.

Interviews will be scheduled at a time that is convenient for the participant and will be conducted by telephone to avoid prohibitive travel costs, as donors will likely be spread across large geographic distances. Project interviewers have been or will be trained in qualitative interviewing techniques and will be supervised by Dr. Maliski, who is experienced in qualitative interviewing. Participants will be reminded that their participation is voluntary, that they have the right not to answer questions they wish not to discuss, that interviewers will be sensitive to fatigue or discomfort, and that their responses will be kept completely confidential. Participants will also be reminded that interviews will be recorded, and informed when recording begins and ends. All participant identifiers will be removed from transcripts during transcription and all data will be secured in locked or password-protected files.

B. Sources of Materials

Data collected from participants will include an in-depth interview about their experience regarding their decision to become a non-directed or bridge donor, which will be digitally recorded and transcribed verbatim. It will also include valid and reliable measures of health related quality of life (HRQOL), depression, and anxiety, which will be selected with input from the advisory committee and administered orally after the qualitative interview. Demographic information collected will include sex, age, race/ethnicity, education level, income, marital status, type of donation considered, time since donation decision, and time since donation, if applicable.

C. Potential Risks, Risk Minimization, and Benefits

The risk for loss of privacy is always present in any study; risks to participants will be minimized through the efforts of the study team. All study team members will have undergone privacy, confidentiality, and HIPAA training prior to their interaction with human subjects or data elicited from human subjects. Written consent documents will be kept in a locked cabinet in a locked office separate from de-identified study data. Interviews will be recorded digitally, and immediately after interviews are complete, the files will be downloaded to password protected files stored in a folder accessible only to the study team on a secure server and securely deleted from the digital recorder. Transcripts of interviews will have all identifiers removed during transcription, and resultant files will be stored in a folder accessible only to the study team on a secure server. All data will be coded by subject number. All interactions with human subjects and data elicited with human subjects will be conducted by the research team.

The potential risk to participants, including the risk for loss of privacy, is minimal in this study. Interviews will be conducted in a respectful and non-judgmental manner to minimize embarrassment and discomfort. Participants may decline to answer any question or questions that they choose. Should significant discomfort arise, the interviewers will be trained to handle such emotional distress. All participants will be provided with written and verbal information about the research study. Provisions will be made to refer subjects to the Principal investigators if participants have questions about their kidney donation-related treatment. After completion of data collection, the participant list will be retained by UCLA, but subjects will not be identified in analyses or publications. The data from subjects will include demographic data, individual interviews, and responses to quantitative instruments. The decision to participate or not will not alter the routine care provided to the patients by any of the study investigators.

D. Adequacy of Protection against Risks

The research team will work closely with the institutional review board to ensure that the rights of the participants are protected. The following steps will be taken to minimize a breach of confidentiality and protect participants: (1) All project staff who have access to identifiable data and who have not already done so will be required to undergo privacy, confidentiality, and HIPAA training; (2) Data safeguarding procedures will be instituted (e.g., direct identifiers will be replaced by code numbers, access to information associating code numbers with identities will be restricted, when analysis of the data is conducted, the participant’s name or other identifying information will not be associated with the interviews in any way); (3) Information that can be
associated with subject identities will be retained for only a limited period (e.g., such information will be destroyed upon receipt of the data or at the end of the project); and (4) Ongoing oversight of the research will be conducted by the institutional review board. All contact and consent materials will be adapted for low literacy so that economically and educationally disadvantaged participants will be able to fully understand and use the information sent to them. Verbal and written consent will be obtained from all participants. Each participant will have an opportunity prior to the start of the study to ask questions regarding the research and their rights as research participants. Each participant has the right to refuse to answer any question that he does not wish to answer. All interviews will be audio taped with the participant’s permission, and participants will be notified when recording begins and ends. Participant identifiers will be redacted upon transcription. Once the research has been completed, the data will be retained for three years and then destroyed, as per UCLA policy.

Because we intend to collect data on mental health (i.e., depression and anxiety), there is the potential for the identification of possibly clinically significant mental health problems during the course of an interview. We take these concerns very seriously, and have policies in place for immediate action should concerns arise. If the interviewers or study coordinator notice particularly high scores on measures of anxiety or depression, or hear any indications during the qualitative interview that may indicate suicide ideation or related concerns, the interviewer or study coordinator will be kept the participant on the line and to contact Dr. Maliski or Veale, who will speak to the participant for evaluation. Dr. Maliski is a trained nurse with many years of experience, and has the ability to evaluate the situation and choose an appropriate course of action. Potential courses of action include reference of the participant to appropriate mental health hotlines, reference of the participant to a local mental health professional, or calling local emergency mental health services, although each situation will be unique and deserve individual consideration. Dr. Maliski will make herself available for these emergencies, but if for some reason the interviewers or study coordinator are unable to reach her, they will be trained to attempt to reach Dr. Veale, to evaluate the severity of the situation, and to call appropriate emergency health services if needed. Dr. Maliski and/or Dr. Veale will follow up with participants as needed to ensure that they are receiving the mental health services they need.

E. Potential Benefits of the Proposed Research

In terms of benefits of study participation, there are several that may apply. There will be a modest incentive of a $20-15 gift card for participation. Interview participants will be given the opportunity to discuss their circumstances with an interested interviewer. The participants will also know that, while they may not benefit directly from their participation, their input may benefit society through a better understanding of the experiences and decisional processes of people deciding whether to altruistically donate a kidney, which may help in the development of strategies and educational materials to increase the number of altruistic donors and to improve the experiences of these donors. An increased number of altruistic kidney donors would decrease the vast need for kidney transplants across the country.

F. Importance of the Knowledge to be Gained

Given the immense cost of dialysis and the over 90,000 patients on the waiting list for kidney transplant, it is essential to discover routes toward increasing the number of available kidneys. An improved understanding of the decisional processes and the experiences of people who choose to donate and who choose not to donate will be instrumental in designing donor recruitment and educational materials, as well as methods for improving the experience of altruistic kidney donation.

Adverse Event Reporting

This protocol is non-invasive and does not present known risk of protocol-related injury. It does not involve the administration of any drug, investigational device or medical treatment. The Principal Investigators, Drs. Maliski and Veale, assume primary responsibility for data safety monitoring on this protocol. No adverse events are anticipated, however, all adverse events will be reported to Drs. Maliski and Veale. Serious adverse events will be reported verbally and in writing to the Principal Investigators within 24 hours of occurrence or identification. Unexpected (but non-serious) adverse events will be reported to the Principal Investigators within two working days. All research staff associated with this project will be fully briefed on this policy.
**Inclusion of Women and Minorities**

Participants will be recruited for this study regardless of their gender or minority status. Based on the current kidney donation population and experience of Dr. Veale (Principal Investigator), the relevant participant recruitment population consists of about 47% women and 48% people of a minority race/ethnicity. Minorities consist of approximately 14% Latinos, 19% African Americans, 10% Asians, and 5% other races/ethnicities. Because minorities are historically underrepresented in the kidney transplant population, the Principal Investigators will work with the recruitment sites to identify minority donors and people choosing not to donate who may be interested in participating in order to make the study sample as representative as possible.
**Targeted/Planned Enrollment Table**

This report format should NOT be used for data collection from study participants.

**Study Title:** Choosing Altruistic Kidney Donation: A Mixed Methods Approach to Understand Donor Decisions

**Total Planned Enrollment:** 120

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<td><strong>Racial Categories: Total of All Subjects</strong></td>
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</tr>
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</table>

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."
Inclusion of Children

Donors under the age of 21 are extremely rare. Many transplant centers will not consider donors from this age group at all, and others only accept donors under 21 with significantly more screening and counseling, or only in extreme circumstances such as a severely ill sibling. On a search through our databases, there has only been one donor who would be considered eligible for this study in this age group, and one potential donor from this age group who would be eligible. Given their extreme rarity and the likelihood that their experiences will significantly differ from older donors because of the extra screening they receive, we will exclude donors under the age of 21 from this study...
Multiple PD/PI Leadership Plan

The melding of the expertise of the Principal Investigators provides a unique aspect to this study. Dr. Veale, though his academic career is in its early stages, has extensive experience in transplantation, a vast network of connections in the kidney transplant community that includes numerous patients. His expertise in the logistical, financial and shipment aspects of exchange transplantation are invaluable. Although Dr. Maliski has not previously worked within the kidney transplant community her expertise in the conduct of qualitative-dominant mixed-methods research focusing on clinical populations of low income minority communities will guide study implementation and qualitative analysis. She has extensive experience in developing, conducting, and analyzing qualitative interviews, as well as excellent relationships with trained qualitative interviewers, qualitative research experts, and an experienced research team. The combination of the skills and resources of the Principal Investigators will provide a solid foundation and a unique approach to this study.

Drs. Maliski and Veale recognize the importance of maintaining a strong commitment to the study’s goal and of instituting procedures to ensure effective management of the research grant and the timely completion of the project tasks. They also recognize the unique strengths that each of them brings to the study, and thus the areas of each Co-Principal Investigator’s authority will be based upon these strengths.

Organizational Structure

Dr. Veale will be the authority and primary point of contact for all members of the kidney transplant community. He will be the liaison to the advisory committee and all recruitment sites and will organize all study activities related to these. This includes directing study coordinators in recruitment activities, ensuring that all study materials make clinical sense in the context of kidney transplantation, and being available to participants for any study-related questions. Because he is already well versed in the transplant literature, Dr. Veale will head the manuscript writing effort, working closely with Dr. Maliski to ensure that the interpretation of qualitative data is concordant with grounded theory.

Dr. Maliski will be the authority and primary point of contact for study administration. Because she has worked extensively with the study team in the past, Dr. Maliski will supervise and train the interviewers and be their point of contact for any questions that arise, although any clinical questions from participants will be forwarded to Dr. Veale. Although Dr. Maliski will head the qualitative data analysis effort, she and Dr. Veale will work closely together on interview analysis to ensure that participant responses are understood in the context of their transplantation experience.

Should any occasion arise where the precedence of authority is unclear, the Principal Investigators will discuss the matter thoroughly and come to a joint decision, meeting with the study team and/or the advisory committee as appropriate.

Project Communication

Ensure effective communication. One of the key responsibilities for Drs. Maliski and Veale will be to maintain effective communications among UCLA research staff, between UCLA and the Advisory Committee, and the funding agency throughout the duration of the project. The UCLA study coordinator will manage all communications among research team members, Advisory Committee members, and the funding agency. Drs. Maliski and Veale will rely on their established infrastructure to ensure effective communication. This infrastructure allows for timely dissemination of information to all parties, including e-mail distribution lists, schedules for routine contacts among the research team, and procedures for responding quickly to inquiries. The communication infrastructure at UCLA is well equipped to support these activities.

Project meetings. The research team will meet monthly or as needed to ensure high-quality and timely progress of the research. These meetings will be attended by Drs. Maliski and Veale and their designated research staff, Advisory Committee, and UCLA administrative staff, as appropriate. An agenda for each meeting will be distributed electronically prior to the meeting so that team members can attend only the parts of the meeting relevant to their responsibilities. At all team meetings, we will continue the practice of taking minutes and generating a list of action items. These minutes serve as logs for the status of project tasks at any given time. Action items are carried forward until the relevant tasks are completed.
Conflict Resolution
Should any conflicts arise between the Principal Investigators that cannot be resolved by mutually respectful discussion, the issue will be brought to the study team meeting or to the advisory committee as appropriate. These forums will allow for outside, unbiased perspectives on the issue. In the realm of study administration, Dr. Maliski will have the final authority, while in the realm of contact with the kidney transplant community Dr. Veale will have the final authority. The study team and/or the advisory committee will weigh in should the area of authority be unclear in a conflict.
References


June 16, 2013

Jeffrey L. Veale, MD
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

I am proud and honored to accept a position on the advisory committee for your study of actual and potential altruistic kidney donors. After reading the grant proposal that you sent to me via email, I believe that this research will give voice to stories that need to be heard and through those stories, give important insight into the decisional process of an altruistic donor that can be used to reach out to those who may donate in the future.

I am eager to bring my perspective as a bridge donor to the development of the qualitative interview guide and the selection of the quantitative measures for this study. My husband was on dialysis for 5 years before he received a kidney. I watched the life drain out of him before my eyes while knowing that it would be nearly impossible to find a compatible donor with his extremely high levels of antibodies. I was unable to donate to him myself, but through chain donation, we found a kidney against all odds, and I was able to pass the generosity that saved my husband on to another person in need. After this experience, I am glad to help you in any way I can to make sure that other families get their miracle too.

We have worked toward this goal together many times in the past and I am greatly looking forward to doing so again. As you are well aware, I am always eager to support you in all of your endeavors.

Sincerely,

Fern L. Bloom

Fern L. Bloom
June 16, 2013

Jeffrey L. Veale, MD
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Jeffrey L. Veale,

It will be my pleasure to serve on the advisory committee for your study of potential and actual altruistic kidney donors. I have read the grant proposal which you emailed me, and I am looking forward to working with you and the committee on this project.

As a member of the advisory committee, I will have input on the development of the qualitative interview guide as well as the survey measures to be included in the study. I will assist in the dissemination of the results of this study upon its completion and will bring a unique perspective that my experience as a recipient in a domino-paired donation chain has given me, as well as the passion for the subject that I have gained through the impact kidney donation has had on my life. Because of my exceedingly high levels of antibodies when I received donation, my chances at finding a matching donor were astronomical. Domino-paired donation gave me a chance at life when it seemed that I had none, and I am proud to do what I can to increase the number of donors who choose the domino-paired route so others can receive the blessing that I received.

My experience with kidney transplantation changed -and saved- my life. I’m happy to help ensure that others have a similarly rewarding experience - and that others have the experience at all.

Sincerely,

Ross Bloom

Ross Bloom
June 24, 2013

Jeffrey L. Veale, MD
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

I'm so looking forward to working with you again. I will be happy to serve on the advisory committee for your study investigating the decision processes of potential and actual altruistic donors. In this position, I will work with other members of the committee to advise the development of the qualitative interview guide and the selection of the quantitative measures for this study. I will also gladly do what I can to help disseminate the findings of this research.

and I'm glad to be able to share this experience and the perspective it has given me through serving on your study's advisory committee.

Sincerely,

Tiffany Furuya
June 24, 2013

Jeffrey L. Veale, MD
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

I would be delighted to serve on the advisory committee to your proposed study. I have read over the grant proposal you emailed to me, and I believe that your project is an essential step on the road to increasing the quantity of altruistic kidney donors as well as the quality of the experience for donors and recipients alike.

This advisory committee will be an exciting meeting of minds. Each member is coming from a very different background, but all of us have been impacted by kidney donation in some way or another. I am eager to assist in developing the qualitative interview guide and in choosing the quantitative measures to be used in this study, and when the time comes, to assist in disseminating the findings of this research in any way that I can.

I'm greatly looking forward to helping you and other researchers learn from the lives that have been touched by kidney donation.

Sincerely,

Pam Heckathorn
Kidney Transplant Recipient
June 24, 2013

Jeffrey L. Veale, MD.
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

It is always a pleasure collaborating with you, and I believe that this project will be no exception. I gladly accept a position on the advisory board for your proposed study. I will provide my personal insight on the development of the qualitative interview guide, as well as on the selection of quantitative measures.

As the CEO of OneLegacy, the nation’s largest organ recovery agency, I have overseen a 50%+ increase in the number and lives saved through donation; especially in this most diverse Donation Service Area in the country; through innovative public outreach programs like the Donate Life Rose Parade Float, Latin American Consulate donation programs, and multi-lingual paid media advertising. Additionally, OneLegacy has dramatically improved organ safety by developing the first web-based organ offer system that inspired UNOS DonorNet, was the first OPO to perform prospective TMA-NAT and Chagas and WNV testing in all donors. We have shared our learning by consulting on organ donation in Japan, Australia, Germany, Taiwan, and Korea and I co-founded the Donation Global Leadership Symposium to spread donation innovation worldwide. I am Past President of the Association of Organ Procurement Organization and UNOS Board member and am currently a Board member of the Organ Donation and Transplant Alliance and Founding Board Member of the Donate Life California Registry and Living Donation California Referral Program. Thus, I know well the administrative and logistic difficulties surrounding kidney donation. This understanding will inform my participation in the advisory committee. I will also leverage my role to assist in the dissemination of the results of this study as appropriate.

This study will provide opportunities to systematically investigate the decision processes of altruistic kidney donors, through which we will be able to better understand how to motivate donors and how to ensure that their donation experience is a positive one. Having worked with you in the past, I know that you will ensure that this project is an important and successful one.

Sincerely,

[Signature]

Thomas Mone
CEO
OneLegacy
June 24, 2013

Jeffrey L. Veale, MD
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

I will be glad to serve on the advisory committee for your proposed study. My husband and I have read over your study aims, and I am eager to get to work on this important project.

In my role as an advisory committee member, I will contribute to the development of the qualitative interview guide and the selection of the quantitative measures for the study. In my role as an advocate for kidney disease, I will also assist in the dissemination of the study results. I am looking forward to brainstorming with the other members of the committee, all of whom have experienced firsthand the great impact kidney donation can have.

Kidney donation changed our entire outlook, and I am proud to help spread this blessing in any way I can. As always, I am greatly looking forward to working with you again. Your passion is inspiring, and I am certain that it will carry this project to a very successful conclusion.

Sincerely,

[Signature]

Gail Shaevil
June 24, 2013

Jeffrey L. Veale, MD  
UCLA Urology  
Box 957309, 3361 PVUB  
Los Angeles, CA 90095-7309

Dear Dr. Veale,

It is with great enthusiasm that I accept a position on your advisory committee for the development of the qualitative interview guide and the selection of the quantitative measures to be used in your study. I will also be happy to help disseminate the results of the study upon its completion.

As an advocate for kidney-related medical issues, I am in a strong position to assist with these tasks. I have heard the stories of many others whose lives have been changed by kidney donation, but it was my own experience that began my advocacy.

I’m looking forward to working with you on this project, as well as with the other members of the advisory committee, all of whom have been impacted by your work in the past. With your great dedication and passion, this project will surely be just as important and impactful.

Best regards,

Steve Shaevel
June 24, 2013

Jeffrey L. Veale, MD
Director, UCLA Kidney Exchange Program
UCLA Department of Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

It is my pleasure to offer you and your research team the enthusiastic support of the National Kidney Registry. You have worked tirelessly to make our goal of increasing the availability of living donor kidneys through an incompatible donor registry a reality. Your ideas and advocacy for improving the management of chains and paired exchanges have been a driving force of innovation in our organization, and it is always a joy to work with such a dedicated collaborator.

Our registry has generated a large amount of information in the course of operation. We have facilitated over 740 transplants within 140+ chains since our matching system was launched in late 2007. In addition to information for the participants in these chains, we also have information on those still waiting to be matched. Very little analysis has been done on this data, and we believe that much can be learned from your planned qualitative interviews with donors.

We are greatly looking forward to the valuable insights that you and your research team will provide with the use of our data.

Sincerely,

Joe Sinacore
Director of Research and Education
National Kidney Registry
c. 201-962-3186
t. 800-401-8919
js@kidneyregistry.org
June 24, 2013

Jeffrey L. Veale, MD.
UCLA Urology
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Dear Dr. Veale,

I am greatly looking forward to serving on the advisory committee to your study of altruistic kidney donors. We have collaborated many times in the past, and as you know I am a great admirer of your work. After reading the grant proposal that you emailed me, I am certain that this will be another productive and essential project.

In my role as an advisory committee member, I will have the opportunity to meet with other stakeholders in the kidney transplant community to brainstorm and discuss the development of the qualitative interview guide and the quantitative measures to be used in this study. Each member of this committee will bring a unique perspective to this endeavor. I will bring the expertise that I have gained as the Vice President of Communications at OneLegacy, Chairman of the Living Donation California Board of Advisors, and Board Member for Explore Transplant non-profit. This expertise will also be useful after the research is complete, when I will be happy to assist in disseminating the findings.

It is essential to better understand the experiences of actual and potential altruistic donors in order to increase altruistic donation and improve the quality of the donation experience, thus working toward closing the gap between kidneys needed and kidneys donated. It is always a pleasure to work with you, and I believe that this project, like our previous collaborations, will have important and impactful implications. As always, I am looking forward to working with you again.

Sincerely,

Bryan Stewart
May 29, 2013

Jeffrey L. Veale, MD.
UCLA Urology.
Box 957309, 3361 PVUB
Los Angeles, CA 90095-7309

Sally L. Maliski, PhD, RN, FAAN
UCLA Sch of Nurs
BOX 956918, 2-256 Factor Bldg
Los Angeles, CA 90095-6918.

Dear Drs. Veale and Maliski,

I will be delighted to serve as a consultant on your proposed project, “Altruistic Kidney Donation: A Mixed Methods Approach to Understand Donor Choice.” As you know, my research focuses on transplant decision-making for direct deceased and living donation. I also design health education resources for patients with end-stage renal disease and their support network, some of whom could become potential living donors. I have developed a number of educational and decision-making tools, including brochures and videos, to address the many barriers to transplantation that these patients face. My transplant education is used in over 1000 dialysis centers in the country.

As a national transplant education expert, I am clear that potential altruistic living donors are still not making informed decisions about the options of non-directed and bridge donation, often because education about these options is lacking. The availability of these types of donors in your area provides us with an exciting opportunity to learn more about their decision-making and educational needs. The proposed project will build the foundation upon which work like mine can be extended so that we may better screen, educate, and recruit these altruistic donors.

In my role, I will be happy to advise the planning, execution, and analysis of this project, including providing my expertise on measurement and educational development. I will attend Advisory Committee meetings by teleconference and review all study and educational materials. As detailed in the budget pages, I understand that I will receive a yearly honorarium.

This is an exciting and well-designed project, and I am very much looking forward to being a part of its success. I am particularly looking forward to the opportunity for collaboration on educational and decision-making tools stemming from this work upon its completion. I am certain that this project is the beginning of a very productive partnership.

Sincerely,

Amy D. Waterman, PhD
Associate Professor of Medicine
Washington University School of Medicine
Resource Sharing Plan

The main resource produced through this study will be the explanatory framework for altruistic kidney donors’ decision making processes. This resource will be shared widely through publication in peer-reviewed journals and presentation at academic conferences. The members of the advisory board have also volunteered to assist with the dissemination of these results, and through this avenue the descriptive framework will reach several donation and transplant organizations: UCLA kidney transplant program, the largest kidney transplant program in the nation; the California Living Donor Registry, the first living kidney donor registry in the world; and OneLegacy, the organization behind the well known Donate Life campaign. We hope that this framework will provide a foundation for further research on altruistic kidney donors as well as for the development of education and recruitment materials for altruistic kidney donors.
1. Application Type:
From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:
  - [ ] New
  - [x] Resubmission
  - [ ] Renewal
  - [ ] Continuation
  - [ ] Revision

Federal Identifier: NRC14349

2. 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:

3. 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 [ ]
4. * Program Income

Is program income anticipated during the periods for which the grant support is requested?

- [ ] Yes    - [x] 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)*
---|---|---

5. * Disclosure 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)?

- [x] Yes    - [ ] No