

INTRODUCTION TO REVISED APPLICATION

Thank you for the very helpful critique and laudatory score of on my initial K23 application. All suggestions have been addressed in the body of the grant. I look forward to your thoughtful review.

Candidate and Environment No concerns raised.

Career Development Plan/ Career Goals/ Mentoring Plan

- Career Development Plan not well developed: As suggested, the large table outlining the 5-year time span was deleted and more specific description of the career development plan is included.
- Candidate-Mentor interactions not specified: I will meet with my UAB mentorship team no less than biweekly. I will have monthly teleconference and yearly face-to-face meetings with my external mentors.
- Details on the MSPH program not provided: Required and elective coursework is now described. Completion of the listed coursework will manifest in a MSPH degree, anticipated after year 3 of the award.
- Future research plans unclear: I anticipate utilizing the data generated from this K23 award to inform a R01 application measuring the effectiveness of a community-based intervention to increase organ donation.

Research Plan

- Plan not hypothesis driven: Based upon data generated from the 1-year pilot project sponsored by the MHRC described above, I have now included hypotheses to be tested with the mixed-methods research.
- Participation concerns: Although I cannot guarantee sufficient participation, I was very successful in recruiting 87 African American volunteers from 6 counties for 6 focus groups for my pilot project. The target participants for this study, however, will be solicited via a different mechanism (mailing a postcard). We are offering a very generous \$100 stipend for participation and will have a large pool of newly registered African American to form the focus groups. Dr. Fouad, my primary mentor, is also the Director of a university-wide Recruitment and Retention Shared Facility that assists UAB investigators with recruitment of minority participants into research studies. She is nationally known for her successes in recruitment and retention of African Americans into large clinical trials and other research projects (see list of publications).
- Applicant role in focus groups: My mentors, who have expertise in qualitative research, have advised that I should not personally conduct the focus groups, as this may introduce bias. The focus groups therefore will be conducted by Dr. Theresa Wynn, an experienced African American moderator from the UAB MHRC. However, I will participate in the development of the questions and the interpretation of results.
- Qualitative researchers not identified: Drs. Ivankova and Schoenberger will perform the qualitative analysis.
- Mechanism of qualitative analysis not described: A detailed description of the mechanism for entering, coding, and analyzing the qualitative focus group data has been added.
- Focus group topics not described: The focus group topics were generated from the relevant constructs of the Social Cognitive Theory. The written survey incorporates two established African American organ donor questionnaires: the Minority Organ Tissue Transplant Education Program 8 question item(1, 2) and the Organ Donor Readiness Index 9 question item(3, 4). Copies of the preliminary oral and written questions have been included in other attachments section.
- Generalizability: We are going to great lengths to generate a study population of African Americans that visited the DMV and made the decision (yes or no) to become an organ donor, because we believe that this is a truly representative population in which we can best study the behavior of organ donor registration.

Mentor/ Co-Mentor

- Mentor interactions: More detailed explanation is provided of the specific roles of mentors and how they will teach/ advise the applicant. External co-mentors are now consultants; they will address “big picture” items pertinent to their content expertise and will function above and beyond my core UAB mentorship team.
- Prior trainees: Current positions for former mentees are included for each mentor and consultant.

Other

- Travel budget excessive: The budget has been revised, including reducing the travel budget.

Program Director/Principal Investigator (Last, First, Middle): DuBay, Derek A.

- Training in the Responsible Conduct of Research plan unacceptable: This plan has been completely revamped in accordance with NIH instructions NOT-OD-10-019, and described in detail in section D.

CANDIDATE INFORMATION

My interest in research began in medical school at the University of Iowa while participating in a student research program, where I first practiced collecting and analyzing data. Later on during my training I gained exposure to different types of research opportunities, ranging from basic science research as a general surgery resident at the University of Michigan to survey-based quality-of-life studies as an abdominal transplant fellow at the University of Toronto. These exposures to research fueled my interest in hypothesis-driven investigation and prompted me to pursue a career in academic surgery. These wide-ranging research experiences have also been central in helping me commit to a career in patient-oriented research.

Upon completion of training, I accepted a position at the University of Alabama at Birmingham (UAB) transplant program. Although the field of transplantation has made remarkable progress, the limiting factor for a life-saving transplant remains organ donation. Every year the number of patients added to the waiting list far outpaces the availability of organs for transplantation. We have a particular challenge involving African American deceased organ donation. There are almost 2,000 African Americans waiting for a kidney transplant at UAB, yet only 26 kidneys were recovered from African American deceased organ donors last year. As I begin my transplant career, it is clear to me that research focus on increasing African American organ donation has a very high likelihood of saving lives and reducing disparities in solid organ transplantation. Increasing organ donation has fundamental relevance to my everyday clinical practice. I believe that this line of research will provide an academically fulfilling, career-long avenue of study. UAB is well suited for this research endeavor. It has the largest population of African Americans on the transplant waiting list and performs the highest number of African American transplants compared to any U.S. program. UAB also has a nationally recognized infrastructure for health disparities research.

The purpose of this Mentored Career Development Award (K23) application is to obtain the necessary tools, support, and mentorship to become a leader in developing, implementing, and evaluating innovative translational research in the field of minority organ donation. As a transplant clinician, I am well positioned via my training and practice to bring together health communication and behavior experts with organ donor recovery teams to forge an effective multidisciplinary collaboration. My goal is to use the opportunities afforded via this award to become an independently funded clinician-researcher and make meaningful contributions in African American organ donation in an effort to reduce health disparities in solid organ transplantation.

A. Candidate's Background

A.1. Current Professional Responsibilities

As an Assistant Professor of Surgery in the Division of Abdominal Transplantation at UAB, my academic appointment is evenly divided between research and clinical responsibilities. Current clinical activities include 1 day in clinic and 1.5 days in the operating room (including elective operations and non-elective transplants). I am in a group practice with 6 other transplant surgeons, facilitating protected research time that is truly free of clinical responsibilities. We have residents, 2 fellows, 10 nurse practitioners, and 2 surgical assistants to facilitate day-to-day care of the transplant patients. Should this application receive support, I will commit 9 person-months per year to the patient-oriented research program by decreasing my clinical activities to 25% effort, including 0.5 days of clinic and 0.75 days of operating time each week.

A.2. Research Training

I participated in a medical student research program at the University of Iowa, and in a dedicated 2-year basic science surgery research fellowship as a general surgery resident at the University of Michigan. In both instances, I was ushered into well-established basic science labs with a track record of mentoring young investigators. While I recognize the importance of basic science research, I have become highly interested in clinical outcomes research. I have participated in several clinical research projects as a resident and as a clinical transplant fellow at the University of Toronto. These research efforts included retrospective chart reviews, database outcome analyses, and survey research. From these experiences, I gained an appreciation for study design, statistical analysis, and data reporting, which has manifested in 16 first-author manuscripts in peer-reviewed journals completed during medical school, residency, and fellowship (5-21). These research experiences have been critical in developing my current research ambitions and have helped me appreciate that I need additional training and formal mentorship to develop a productive and focused academic career.

B. Career Goals and Objectives

My long-term career goal is to become an independently funded NIH T2 translational investigator (22), with a focus on organ transplantation and health disparities. My research goals are to: 1) identify determinants for the positive decision to become a registered organ donor among African Americans; 2) identify determinants for the registered organ donors' decision to inform their family of their organ donation intentions; 3) design and implement successful community-based interventions to increase African American organ donation; and 4) develop as a NIH T2 translational research scientist and leader in the field of solid organ transplantation.

Achievement of these goals would be recognized by a number of benchmarks:

- Designing successful community-based interventions to increase minority organ donation
- Receiving and sustaining extramural funding
- Developing into an independent investigator
- Presenting research findings at national meetings
- Publishing findings in leading peer-reviewed scientific journals
- [Receiving national recognition as an expert in the area of (T2–T4) organ donation/recipients research to address health disparities and improve health outcomes of high-risk populations]
- Fulfilling criteria for promotion

B.1. Scientific Bibliography

Although heterogeneous in nature, my previous research projects have provided important background experiences for the current proposal of investigating health disparities in organ donation. The goal of the proposed career development award is to build on these experiences to become an independent researcher.

Clinical Outcomes. My clinical outcomes research has evolved from small retrospective chart reviews of paper charts or electronic medical records (5, 7, 8, 23) to more sophisticated analyses of large electronic patient databases (9, 10, 17, 24). Additional work required merging databases from different academic, institutional and public sources (16, 25, 26).

Survey Research Methods. While a fellow at the University of Toronto Multiorgan Transplant Program, I performed a quality of life study in patients who had donated the right lobe of their liver for transplantation. I secured internal funding and assembled a collaborative research group with expertise in transplant neuropsychiatry, transplant hepatology, and transplant surgery. My project was met with success manifesting in several oral presentations at national meetings and 4 publications in leading transplant journals.(13, 14, 24, 27) This project introduced me to the complexities of survey research design and statistical analysis, as well as to the challenges of assembling a collaborative research group in which each of the participants feel valued and contribute to the project in a timely fashion. Designing and implementing organ donation interventions will require mixed-methods research techniques and strong leadership skills to assemble and manage a cross-disciplinary research collaborative.

Health Disparities in Organ Donation. I was awarded an intramural pilot grant from the UAB Minority Health and Health Disparities Research Center (MHRC) in the fall of 2009 to study African American organ donation in Alabama. Execution of this project has afforded me the opportunity to develop relationships with several experts in the UAB School of Public Health, UAB Division of Preventive Medicine, and the Alabama Organ Center, as well as contacts in the Alabama Vital Records Department and the Department of Motorized Vehicles. Strong working relationships with these professionals will be vital to the success of the proposed research project. [In the pilot project, 6 focus groups in 3 urban and 3 rural Alabama counties were completed using the Theory of Planned Behavior as a guiding framework. Qualitative and quantitative data was collected on 87 African American participants. I am currently preparing a manuscript based upon the mixed-methods data analysis. Findings will be validated with a quantitative telephone survey. My experiences in this pilot project helped me appreciate the need to investigate a more representative population and also formed the basis of the proposed research design—investigating the actual decision to become a registered organ donor as opposed to hypothetical questioning. Conducting the focus groups and completing the telephone survey in my pilot project helped me gain experiences and skill sets that will be important for the proposed research project, which utilizes similar mixed-methods research approaches.]

C. Career Development/ Training Activities

This award will provide support for me to acquire the research skills and experiences necessary to develop into an independent investigator. The coursework and mentoring are focused on three areas central to the aims of the proposal: mixed-methods research, behavioral science research, and professional development. My primary mentor has helped me identify experts at UAB to mentor my development for each of these research domains (see E. Mentorship Plan). I will have scheduled meetings with each of my UAB mentors on a biweekly basis. [In order to strengthen the research design and carefully construct the mixed-methods measurement instruments, I enriched my local mentoring team with two external mentors with expertise in the area of health communications/ health behavior research and organ donation research. My entire mentorship team will participate in monthly meetings, with the external mentors participating via telephone conference.]

Didactic Training. The initial timeframe of the award will focus on didactic training so I can gain a better working knowledge in quantitative and qualitative research, behavioral science theory and practice, epidemiologic research, and health communications. I will enroll in the Masters of Science in Public Health Clinical Research in Behavioral Science offered through the UAB School of Public Health. I will take classes full-time the first year of the award and part-time in years 2 and 3, [culminating in a MSPH degree.] This training will be invaluable for steering my career and future research. However, I do not intend to become a behavioral scientist with this education. The purpose of this training in behavioral science is to strengthen my research capabilities to use in concert with my clinical discipline of transplantation to ensure a productive academic research career. I anticipate close collaborations with research behavioralists and biostatisticians for post-Career Development Award projects. Details on the MSPH program are provided below:

[MSPH in Clinical Research in Behavioral Science (41 Credit Hours Required):

Core Required Courses (14 Credit Hours): Biostatistics I, Biostatistics II, Design and Conduct of Clinical Trials, Epidemiology of Clinical Research, Topics in Clinical Research.

Masters Research Electives (9 Credit Hours): Advanced Theory and Practice in Behavioral Science, Grant Writing, Data Management/ Reporting with SAS

Behavioral Science Electives (9 Credit Hours): Health Communications, Research Methods and Evaluation, Qualitative Research Methods

Masters Directed Research (9 Credit Hours)]

Mixed Methods Techniques. UAB Mentor: David Redden, PhD

The proposed career development curriculum includes didactic education to obtain advanced knowledge in mixed-methods research, including quantitative and qualitative research methodology, statistical modeling, and survey development. I will take the following coursework: EPR 596 Qualitative Research Methods, BST 621 Biostatistics I (SAS-based), BST 622 Biostatistics II (SAS-based), BST 625 Design and Conduct of Clinical Trials, BST 626/626L Data Management/ Reporting with SAS, and HB 642 Research Methods and Evaluation. After receiving a very favorable score on my initial K23 application, my department made a 10% salary effort commitment to secure Dr. Redden's time and expertise, averaging 4 hours per week. Dr. Redden currently comes to my office weekly to review data and complete analyses for ongoing projects. These meetings will continue. Furthermore, we envision that when I begin taking SAS-based Biostatistics I and II, I will begin performing the statistical analyses myself, under Dr. Redden's mentorship and oversight.

Behavioral Science, Epidemiologic Research, Health Communication. UAB Mentor: Connie Kohler, DrPH

The proposed career development curriculum includes didactic education in epidemiology, behavioral science theory, and health communication. I will take the following coursework to obtain advanced knowledge in these fields: EPI 607 Epidemiology of Clinical Research, EPI 680 Topics in Clinical Research, HB 624 Advanced Theory and Practice in Behavioral Science, HB 630 Health Communication, EPI 703 Grant Writing, and HB 698 Masters Directed Research. I will attend monthly health behavior seminars offered during the school year via the UAB School of Public Health. I currently meet with Dr. Kohler the third Wednesday of the month, 10am-12pm, as part of the current project we are completing. These meetings will increase to biweekly upon being awarded this grant. The meetings will emphasize behavioral science theory, health communications, epidemiology, and methodology. Early in the award, I will attend a 4-day workshop retreat on focus group research strategies by Dr. Richard Krueger, an international focus group expert.

[The two external mentors, Drs. Siminoff and Holt, will provide guidance in this research domain. These mentors have been extremely successful securing external funding and are widely published. Dr. Siminoff is perhaps the leading health communications expert with regards to organ donation in the U.S. As a content expert in organ donation, Dr. Siminoff will provide mentorship primarily regarding study design and data interpretation. Dr. Holt has specific expertise in health behavior theory and research. As an expert in theory-driven mixed-methods health behavior research, Dr. Holt will provide counsel in study design and data interpretation as well as manuscript construction specific to health behavior research. There will be monthly meetings among the entire mentorship team, with Drs. Siminoff and Holt participating via teleconference. I will also have yearly face-to-face meetings with Drs. Holt and Siminoff at their respective academic institutions. Drs. Holt and Siminoff will provide mentorship on “big picture” items, whereas my local UAB mentor, Dr. Kohler, will provide day-to-day mentorship on health behavior science.]

Professional Development. UAB Mentor: Devin Eckhoff, MD

There will be a variety of activities to foster professional development in the fields of health disparities, public health, and organ donation. I will attend the UAB public health lecture series that consists of quarterly distinguished guest lectures. I will also attend and actively participate in the weekly Alabama Organ Center donor review in which all heart-beating donor referrals are discussed. The Alabama family support specialist coordinators attend this meeting; details of the approach/discussion with potential donor families are reviewed in detail. Dr. Eckhoff is my co-mentor for professional development. I currently meet formally with Dr. Eckhoff weekly (although we interact multiple times each week due to common clinical practices). Our structured meetings focus on reviewing data, project developments, and professional development in the fields of clinical organ donation and solid organ transplantation. Dr. Eckhoff helped me obtain national representation in the American Society of Transplant Surgeons as a 3-year member of the Ethics committee. Dr. Eckhoff is the Medical Director of the Alabama Organ Center and is making efforts to increase my exposure to the policies and procedures of organ donation locally and on a national level. I will attend and present my research at annual transplant, organ donation, and public health national meetings.

Transition to Independence. Primary UAB Mentor: Mona Fouad, MD, MPH

I will attend biweekly structured meetings with Dr. Fouad, my primary mentor for this Career Development Award. These meetings will focus on monitoring my career development plan, reviewing data, publishing results, and timely execution of the research program. I will participate in enrichment activities through the UAB Minority Health and Health Disparities Research Center (MHRC): monthly health disparities seminars and workshops and annual research symposium. I will be expected to present my research data once a year at the MHRC seminars. I will also participate in the UAB MHRC Health Disparities Research Training Program. This one-year program for junior faculty links scholars with mentors and independent investigators. The program provides opportunities for networking and collaboration with established MHRC researchers and scientists. The program consists of twice-a-month videoconference seminars on research design and methods, bioethics workshops, courses in epidemiology and biostatistics, and grant-writing and manuscript-writing retreats.

[Future Research Plans. I plan to use the data obtained from the proposed mixed-methods research to design a large-scale community-based intervention to increase African American organ donor registration and family notification. I anticipate applying for an R01 on this topic during year 4 of this award. I believe the mentorship, coursework, education, and exposures afforded via this Career Development Award will put me in an excellent position to forge a productive collaborative relationship between professionals from clinical transplantation and organ donor recovery teams, on the one hand, and health behavior and community-based intervention researchers, on the other. The MSPH- degree coursework was specifically chosen to provide an educational framework for conducting a community-based intervention. The focus groups and telephone survey will be designed to give insight on the best approaches to provide organ donor education and the optimal venues to increase African American organ donor registration. Furthermore, the career development enrichment activities were purposefully chosen to give me exposure to health disparities research and ongoing community-based health education interventions in Alabama. UAB has a rich network of ongoing clinical trials targeting rural and urban African American populations. I will to gain significant exposure to this research, setting the groundwork for future collaborations.]

[D. Training in Responsible Conduct of Research]

I completed the institution-specific responsible conduct of research requirements while at the University of Iowa, University of Michigan, University of Toronto, and presently as a faculty member at UAB. I have also completed and have active certification in the NIH—Protecting Human Research Participants training.

The UAB Center for Clinical and Translational Science has an established program fulfilling the requirements as outlined by NIH Notice Number NOT-OD-10-019.(28) This program offers a mixture of training venues including standard annual IRB investigator training, an annual ethics conference retreat, and bioethics workshops as part of a health disparities research training program, quarterly ethics and values in the sciences enrichment experiences, and an online course of research ethics centered on case-based vignettes.

During my Career Development Award, I will maintain active NIH-Protecting Human Research Participants training and annual UAB IRB investigator training certification. I will attend the annual ethics conference retreat and participate in the ethics and values in the sciences enrichment experiences quarterly conferences during each year. I will also complete the 1-year Minority Health and Health Disparities Center Research Training Program during year 1 of the grant, which includes bioethics workshops specific to health disparities research. Finally, I will complete the research ethics online course at the beginning of the training period and update the training as suggested by the UAB Center for Clinical and Translational Science.

UAB IRB Investigator Training. Annual participation in this 4-hour course is required of all key personnel involved in human subjects research. The course objectives are to provide an introduction to behavioral and biomedical research ethics and current institutional policies regarding human subject research.

Annual Ethics Conference. Sponsored annually by the UAB Center for Ethics and Values in the Sciences, this 20-hour conference covers the following clinical research ethics topics: conflict of interest, authorship, peer review, mentor-mentee relationship, ethically managing data, the ethics of data gathering, human subjects and live vertebrate animal subject research, industry collaborations, misconduct, and research fraud.

UAB MHRC Health Disparities Research Training Program. This 1-year program offered through the Minority Health and Health Disparities Center will be completed in year 1 of the grant. The training program includes bioethics workshops specific to health disparities research.

Ethics and Values in the Sciences Enrichment Experiences. This quarterly conference sponsored by the UAB Center for Clinical and Translational Sciences utilizes faculty to present various ethics topics via didactic and small-group discussions. Recent topics include ethical issues in clinical trials and good and bad practices in image manipulation.

Research Ethics Online Course. Additional instruction in the responsible and ethical conduct of research will be obtained by participation in the UAB Center for Clinical and Translational Science: Responsible Conduct of Research online course. This is a web-based instruction and certification program of research ethics centered on case-based vignettes.

Description of the Institutional Environment

University of Alabama at Birmingham School of Medicine (UAB)

The School of Medicine at UAB is dedicated providing outstanding medical care and services and the enhancement of new knowledge through clinical and basic biomedical research.

School of Public Health

The UAB School of Public Health is comprised of 84 faculty members in Departments of Biostatistics, Environmental Health Sciences, Epidemiology, Health Behavior and Health Care Organization and Policy.

Division of Preventive Medicine

The Division of Preventive Medicine focuses on research and clinical activities that reduce or prevent chronic disease. This division has 24 physician faculty members and 250 staff. There are currently over 89 active projects with award amounts totaling more than \$144 million in funding from the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Veterans Administration (VA).

Division of Abdominal Transplant Surgery

UAB Division of Transplant is an accomplished multi-organ transplant program with comprehensive clinical coverage and superior 1 and 3 year patient outcomes. The transplant program typically performs between 250-300 kidney, 20 pancreas, and 100 liver transplants each year.

UAB Centers

Minority Health and Health Disparities Research Center (MHRC)

The UAB Minority Health and Health Disparities Research Center (MHRC), housed in the Division of Preventive Medicine, is University-Wide Interdisciplinary Research Center focused on eliminating the health inequalities experienced by racial and ethnic minorities locally, regionally, and nationally. The priorities of MHRC are encompassed within three programs: Research, Training/Career Development, and Community Outreach. As a University-wide Interdisciplinary Research Center, the MHRC is supported by ten UAB schools and has 200 faculty members, 16% of which African American and 15% Hispanic.

The role of the MHRC in this research project is to 1) link this research effort with community organizations, State agencies, and minority-serving institutions with which the MHRC has a strong relationship, and 2) link this research effort with African American populations.

Facility for Access to Clinical Enrollment Services (FACES)

FACES, housed in the Division of Preventive Medicine, is a facility supporting the MHRC Recruitment and Retention Core. The strong community outreach and educational services of FACES help overcome barriers to participation in underrepresented populations. By using innovative recruitment techniques and culturally appropriate recruitment materials, the facility successfully engages participants from minority communities.

The FACES infrastructure will be utilized in this study for formative research services, including 1) focus group planning, recruitment, and execution; and 2) completion of the telephone survey

[Center for Clinical and Translational Science

The National Center for Research Resources-sponsored Center for Clinical and Translational Sciences (CCTS) is a UAB institutional research center offering an institutional research infrastructure to enhance the efficiency and quality of clinical and translational research. One of the missions of the CCTS is to provide Career Development Resources to facilitate attaining and completing a K award such as this application.

The CCTS Research Commons will be utilized for Career Development Resources and specifically to provide training in the responsible conduct of research as described by the NIH.]

External Participating Organizations

Alabama Organ Center (AOC)

The Alabama Organ Center (AOC) is the sole federally designated organ and tissue procurement organization for Alabama. The AOC procures an average of 125 organ and 400 tissue donors and tissue each year.

The AOC will 1) provide Dr. DuBay with access to the Alabama organ donor registry and 2) include Dr. DuBay in the weekly AOC donor review in which all the heart beating donor referrals are discussed.

**SUMMARY STATEMENT
(Privileged Communication)**

Release Date: 07/15/2011

PROGRAM CONTACT:
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Application Number: 1 K23 DK091514-01A1

Principal Investigator

DUBAY, DEREK A MD

Applicant Organization: UNIVERSITY OF ALABAMA AT BIRMINGHAM

Review Group: DDK-D
Kidney, Urologic and Hematologic Diseases D Subcommittee

Meeting Date: 06/21/2011
Council: OCT 2011
Requested Start: 09/01/2011

RFA/PA: PA10-060
PCC: KTR KTR
Dual PCC: HHE N
Dual IC(s): HL

Project Title: Increasing African American Organ Donation: Donor Registration & Family Consent

SRG Action: Impact/Priority Score:

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

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

Gender: 1A-Both genders, scientifically acceptable

Minority: 2A-Only minorities, scientifically acceptable

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

Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated
1		
2		
3		
4		
5		
<hr/>		
TOTAL		

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

ADMINISTRATIVE NOTE

SCIENTIFIC REVIEW OFFICER'S NOTES

RESUME AND SUMMARY OF DISCUSSION: This resubmission application was submitted in response to program announcement PA-10-060 entitled Mentored Patient-Oriented Research Career Development Award (Parent K23)". The overall goal is to increase organ donation among African Americans by studying factors affecting registration as an organ donor and notification of the family. The proposed studies address an important area of disparities in organ transplantation/donation. Previously noted strengths such as the exceptional productivity of the candidate, the excellent mentoring team, and the outstanding institutional support to the candidate's research remain. The candidate has responded satisfactorily to many of the critiques raised by previous reviewers. The career development and research plans have been improved and concerns about the feasibility of the proposed research have been partly mitigated by a success of pilot study. Lingered weaknesses of the application include a lack of the preliminary data and unclear rationale in support of the hypotheses, and a discrepancy between the candidate's career goals and the proposed training activities. The strengths outweigh the weaknesses and, overall, this application is rated excellent.

DESCRIPTION (provided by applicant): Rationale: Compared to Caucasians, African Americans are less likely to become registered organ donors. In addition, although first-person consent laws have been passed in 48 states, hospitals remain reluctant to harvest organs without the consent of the registered donor's family. Epidemiologic studies on African Americans have focused on the willingness to donate organs. Little research has been done on the positive decision-making process of becoming a registered organ donor. Objectives: The goal of this project is to identify facilitators associated with becoming a registered organ donor and providing familial notification. We hypothesize that positive outcome expectations (physical, social, and self-evaluative) will be associated with increased African American organ donor registration. We also hypothesize that increased perceived self-efficacy (PSE) will be associated with increased familial notification. Design and Methods: Using the Social Cognitive Theory as a guiding framework, a qualitative study involving focus groups will be performed and then validated by large-scale quantitative telephone surveys. African Americans, age 19 and older, who made a decision regarding organ donation at the Alabama Department of Motorized Vehicles within the past 3 months will be stratified into those who chose to become a registered organ donor and those who declined. The dependent variables for analysis will be 1) becoming a registered organ donor and 2) family notification of the decision to become a registered organ donor. Significance: The study will identify the key factors that drive African Americans to become registered organ donors and the determinants of familial notification. This data will inform future interventions to increase African American donor registration and develop mechanisms to ensure family consent, thereby reducing disparities in organ donation and improving the health outcomes of African Americans.

PUBLIC HEALTH RELEVANCE: African Americans who registered at the Alabama Department of Motorized Vehicles within the past three months will be stratified into those who chose to be an organ donor and those who declined. A qualitative study involving focus groups and validated by quantitative surveys will be performed to determine the factors associated with the decision of African Americans to become registered organ donors and to inform their families of their donation wishes.

CRITIQUES

(Note: The critiques below were prepared by the reviewers assigned to this application. These commentaries and criterion scores do not necessarily reflect the position of the authors at the close of the group discussion, nor the final majority opinion of the group, although reviewers are asked to amend their critiques if their position changed during the discussion. The resume and other initial sections of the summary statement are the authoritative representation of the final outcome of group discussion. If there is any discrepancy between the peer reviewers' commentaries and the priority/impact score on the face page of this summary statement, the priority/impact score should be considered the most accurate representation of the final outcome of the group discussion.)

CRITIQUE 1:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment Commitment to the Candidate:

Overall Impact: The candidate and the environment are outstanding. The candidate's publication record is exceptional (although they are not related to the proposed area of study). The mentoring team is excellent and the career development plan is much better described and how the candidate will interact with the mentoring team is now described in more detail. The progress in the pilot study and the ability to recruit patients for the pilot study document the feasibility of the proposed studies. The institutional support for the candidate is outstanding.

1. Candidate:

Strengths

- The candidate's publication record is outstanding; he has 28 peer reviewed publications (four additional since the last submission) and he is first author on 19 of these.
- The candidate has received several awards including the Dr. Arnold G. Coran Outstanding Medical Student Educator Award (voted by all the M3 Surgical Clerkship students, awarded annually) in 2005, the 2005-2006 Bronze Beeper Award for Medical Student Education (voted by the M3 & M4 students for all clerkships, awarded annually) in 2005-2006, the Dr. Robert Bartlett Award for Excellence in Academic Surgery (voted by the General Surgery Residents and given annually to 1 Chief Resident) in 2006 and the Charles Barkley Health Disparities Research Award Recipient in 2009.

Weaknesses

- Very few of these publications are related to the proposed area of research (minor concern)

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- The career development plan and interactions between the candidate and the mentoring team are much better described.
- The candidate will obtain Master's of Science in Public Health in years 1 to 3 of the award and his course work to attain Master's degree is provided in the resubmitted application.
- The candidate has added a section on future research plans which more clearly defines his pathway to becoming an independent investigator.

Weaknesses

- None noted

3. Research Plan:

Strengths

- The topic to be studied is very important
- The first specific aim is to develop a comprehensive list of successfully registered African American organ donors. Comparisons between those who did and those who did not become donors will be studied by the Social Cognitive theory. The hypothesis is that African Americans who have positive outcome expectations will be more likely to become organ donors.
- The second specific aim is to identify determinants of registered organs donors conveying donation intentions to their families. The hypothesis is that African Americans registered organ donors who have a higher perceived self-efficacy will be more likely to notify their families of their organ donor wishes.

- There is strong support from the DMV; the names, addresses and the appropriate information will be available to the candidate and that it is legal to do so.
- The research plan is hypothesis driven
- The candidate was awarded an intramural pilot grant from the UAB Minority Health Disparities Research Center in the fall of 2009 to study African American organ donation in Alabama. This has allowed the candidate to establish working relationships with many experts and he has recruited 87 African American participants for the focus groups. The pilot study is directed to a hypothetical questioning while the proposed studies are to investigate the actual decision to become an organ donor through the BMV.

Weaknesses

- While the ability of the candidate to enroll 87 individuals in the pilot study is encouraging, a concern remains that not enough individuals will agree to participate.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The primary mentor is Mona Fouad, MD. Dr. Fouad is a well-funded, internationally recognized health disparities researcher and she is Director of the UAB Division of Preventive Medicine and the Minority Health and Health Disparities Center (MHRC). She has mentored several trainees; she list 10 previous trainees who now hold academic positions.
- David Redden, PhD, is a co-mentor with expertise in mixed methods techniques. Dr. Redden has a long track record of successful collaborative relationships with Division of Preventive Medicine and teaches biostatistics in the School of Public Health. Since the initial submission of this application, the candidate's department secured 10% salary effort for Dr Redden to interact with the candidate for approximately 4 hours per week. Dr. Redden lists 6 previous trainees who are now in academic positions.
- Dr. Connie Kohler (co-mentor) is an expert in behavioral science research. She is the director of the UAB Health Communications Unit and teaches HB 624 (coursework for master's program). Dr. Kohler designed the behavior science, epidemiological research, and health communications coursework and contributed to the health behavior research design.

Weaknesses

- None noted

5. Environment and Institutional Commitment to the Candidate:

Strengths

- The environment is excellent for the proposed studies. The UAB Minority and Health Disparities Research Center in the Division of Preventive Medicine is an asset for the proposed studies.
- The Facility for Access to Clinical Enrollment Services supports the Minority Health Disparities Research Center in overcoming barriers to participation and this is an additional strength of the application.
- The Chairman of the Department of Surgery, Dr. Kirby Bland, will provide \$ for each of the 5 years of the award to provide supplemental support. In addition, he will support Dr. DuBay's application for an American College of Surgeon NIH K08/K23 Supplemental Award for\$ per year for 5 years should he receives the K23 award

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C1A - Children and Adults, Acceptable

Vertebrate Animals:

- N/A

Resubmission:

- The candidate has been very responsive to the previous critiques

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- appropriate

Comments on Subject Matter (Required):

- appropriate

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- appropriate

Comments on Duration (Required):

- appropriate

Comments on Frequency (Required):

- appropriate

CRITIQUE 2:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment Commitment to the Candidate:

Overall Impact: This is a revised application for five years of support for a K23 award for Dr. Derek DuBay. Dr. DuBay is an Assistant Professor of Surgery at the University of Alabama at Birmingham and has been fully trained in both general surgery and transplantation surgery. He is a member of the Division of Transplantation and is experienced in kidney transplantation. He has proposed a five-year career development plan that includes the attainment of a Master's degree. He has assembled an extraordinary group of mentors, each with complementary skills to address the specific questions that he has proposed. The area of research is extremely important and addresses the disparities in organ donation between African-Americans and Caucasians. While kidney failure is more frequent in African-Americans, the percentage of African-Americans who have consented to be deceased organ donors may be much lower than that of Caucasians, especially in the applicant's home state of Alabama. The applicant proposes a series of focus groups and telephone interviews of those who have recently attained driver's licenses in Alabama. He proposes to identify the factors that, the individuals indicated, led to their decision to either agree to be organ donors or not. The applicant proposes that this study will provide the basis for subsequent interventional studies which will address the disparities. The strengths of the application include the previous publication record and research work of the applicant, the importance of the area of investigation, the resources available to the applicant at his institution, the

extraordinary group of mentors available to the applicant and the unique design of the research proposal. The weaknesses of the application include the lack of experience of either the applicant or the majority of the mentors in this area of investigation, the lack of preliminary data to support the proposed area of research and the hypotheses, the lack of collaborative efforts of the mentors in the past, the serious concern that those who have chosen not to be organ donors will not participate in the research study, and the lack of any experience of the applicant in interventional trials. The applicant clearly states that he wishes to become a translational researcher who will develop interventional studies to address the disparities in proposed organ donation. The applicant has no experience in interventional studies and his career development plan does not add to that experience.

1. Candidate:

Strengths

- The applicant is a well-trained kidney transplant surgeon who has an extensive publication record. He lists 28 publications in his CV of which he is the primary author of 19. Four of these publications concerning organ donation which is the topic of his current application. One of the publications, which was recently submitted, has been co-authored with several of his proposed mentors for this application.
- The applicant has received several honors and awards, including two Medical Student Educator Awards, an award for academic surgery and the current research support which is Charles Barkley Health Disparities Research Award.
- He received his M.D. degree from the University of Iowa College of Medicine in 1999, completed a general surgery residency at the University of Michigan in 2006 and undertook a transplant fellowship at the University of Toronto which ended in 2008. Since that time he has been an Assistant Professor of Surgery in the Department of Transplant Surgery at the University of Alabama at Birmingham.
- In addition to the Charles Barkley Award, he has a one-year award from the Minority Health and Health Disparities Research Center.
- The applicant has very strong letters of support from his department and from his transplant surgery mentor, Dr. Eckhoff.

Weaknesses

- In the introduction to the revised application, the applicant states that there were no concerns about the candidate. This is not quite true. One of the reviewers indicated that the candidate had a heterogeneous research background which could indicate a lack of focus. This concern remains. Indeed, the applicant's extensive bibliography is primarily related to surgical techniques and case reports. Although the applicant points out that there were several methods of obtaining and analyzing the data in his prior research experience, it is true that he has no experience in interventional studies. The current application will not strengthen that experience. This is a serious concern insofar as the applicant has indicated that his ultimate goal is to undertake interventional trials to attempt to correct what appears to be a lack of minority organ donation.
- A second reviewer indicated that the applicant's prior publications to the most extent were in surgical techniques. The applicant has submitted one manuscript for consideration for publication with his proposed mentors on the topic of this application. Nonetheless, the topic of this application appears to be a radical change from his prior research experience. Given the amount of time and effort required for a surgical residency and career, the author is deficient in not explaining why he will not be using that training in the development of his research career.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- The applicant has addressed several of the concerns raised by previous reviewers regarding the career development plan. He has more completely described the rationale and requirements for the Master's degree that he intends to obtain. However, he indicates that his intention is not to become a behavioral scientist. Therefore, the rationale for the extensive coursework needed for an advanced degree is not clear. Would it be possible to decrease the amount of time needed for course work in order to focus on those topics alone which will be necessary to achieve the desired career development?
- As indicated, the applicant additionally intends to participate in a health disparities training program as well as public health lectures. These are all valuable activities, but the balance of didactic lectures and other teaching forums with actual hands-on research experience needs to be justified.
- The applicant has described in detail how he will interact with each of the mentors and how he plans to have monthly meetings/conference calls in which all of the mentors will participate together.

Weaknesses

- The candidate clearly states that his ultimate goal is to develop a career in translational research. Traditionally, translational research refers to an interface between basic and clinical research. The applicant's outlined career development addresses only a classical clinical, statistical, epidemiologic and behavioral research methods curriculum. Thus, the stated goal of translational research expertise is not well supported.
- Additionally, the applicant clearly states that he intends to develop interventional trials designed to improve African-American participation in deceased organ donation. The applicant has no experience in interventional trials and none of the training or research proposed in this application will enhance that experience. Thus, the proposed career development is lacking in the specific skills that would be necessary for the applicant to reach his stated career goals. The applicant is certainly correct in stating that identifying the root causes for poor participation of African-Americans in organ donation is certainly necessary prior to developing interventions. Nonetheless, a more comprehensive research plan which would accelerate the accumulation of that knowledge and provide the applicant with appropriate experience in interventional trials would be much more appropriate.

3. Research Plan:

Strengths

- The area of research proposed by the applicant is very important and a successful interventional trial would increase the number of deceased organ donations for minority transplant candidates.
- The applicant has obtained collaborative support from all of the major organizations necessary to undertake this research, including all of his mentors, the local organ procurement organization, the Department of Motorized Vehicles, and experienced researchers who will perform the necessary roles for the focus groups. As previously noted, it appears to be inappropriate for the applicant himself to undertake the role.
- As noted in the letters of support, the applicant appears to be very talented in recruiting collaborative research partners.
- The candidate has accumulated an impressive group of mentors, each of which has important skills in the areas necessary for the completion of this research.
- The applicant institution has extensive experience in developing focus groups and in obtaining consent of minorities for various research projects. The assembly of these resources is ideal for this type of research.

Weaknesses

- The previous application was criticized for the lack of hypothesis driven research plans. The applicant has added hypotheses to each of the two specific aims of the research plan. Unfortunately, neither the stated prior publications nor the authors own preliminary data provide any support for the development of these hypotheses. Indeed, the rationale behind the hypotheses is not presented.
- There is no timeline of research accomplishment presented. Indeed, as noted above, one would hope that this application would include at least the development of an interventional trial and perhaps some preliminary work in that area. As it stands, one wonders why it would take five years to accumulate the data proposed in this trial.
- The author has accumulated some preliminary data by having focus groups of African-American volunteers. As he noted, however, this group may not be representative of those who would be involved in the proposed research. Indeed, as the applicant points out, there may be substantial difficulty in recruiting those who have chosen not to be organ donors. There are no preliminary data that addresses this very serious concern.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The applicant has recruited a very strong group of mentors, each with complementary skills. Each of the mentors is a well-established clinician or investigator, and most of them have experience in training postdoctoral fellows.
- Dr. Fouad is Professor of Medicine and director of the Division of Preventive Medicine at the University of Alabama at Birmingham. She is well funded and has collaborated with multiple different investigators. Most of her experience, however, is in the area of cancer and to a lesser extent in the area of diabetes. The proposed research is a new area of emphasis for Dr. Fouad. She has extensive experience in mentoring young investigators.
- Dr. Holt is Associate Professor in the Department of Public and Community Health at the University of Maryland. She is well-funded and she is an experienced researcher. She is an expert in theory-based health communication intervention, particularly serving African-Americans. Most of her research has been in the area of cancer.
- Dr. Kohler is Professor in the School of Public Health at the University of Alabama in Birmingham and an expert in behavioral change. She is well-funded.
- Dr. Eckhoff is the Director of the Division of Transplantation of the University of Alabama at Birmingham and Professor of Surgery. He has participated in several research studies but has not had experience in organ donation.
- Dr. Siminoff is Professor and Chair of the Department of Social and Behavioral Health in the School of Medicine at Virginia Commonwealth University. She is an expert in qualitative methods in multimethod research. She is well-funded and has extensive experience in the area of organ donation.
- Dr. Redden is Associate Professor in the Department of Biostatistics the School of Public Health at the University of Alabama at Birmingham. He has an extensive bibliography and has participated in multiple areas of research, but this is his first attempt to address organ donation.

Weaknesses

- While extensive information has been provided concerning the past training experience of the various mentors, this information does not include details concerning the eventual ability of the trainees to obtain independent research funding. In addition, many of the mentors have had substantial experience in training PhD candidates but less experience in training physicians.
- In his letter of support, Dr. Bland, the Chairman of the Department of Surgery at the University of Alabama at Birmingham indicates that Dr. Fouad has been responsible for the training of

three surgeons at the University of Alabama at Birmingham. Dr. Fouad does not seem to list these individuals.

- There is no track record of these mentors either in the specific area of research proposed by the applicant or in collaboration with each other. As noted, the applicant is particularly skillful in recruiting collaborators for research and he may be able to elicit appropriate participation of all of these mentors in a singular approach to this very important problem. Nonetheless, the lack of previous experience in this area of research by these investigators is a concern.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- University of Alabama at Birmingham is a distinguished organ transplant center with particular experience in transplantation of African-Americans.
- University of Alabama at Birmingham Minority and Health Disparities Research Center is an ideal location for the proposed type of research. In addition, the facility for access to clinical enrollment services is a unique resource and a substantial advantage for this application.
- The institution has proposed that the applicant will have 75% of his time protected for research. Since surgeons are required only to spend 50%, this shows substantial support for this trainee. In addition, additional financial support for the trainee is possible, including a substantial support from an institutional training grant.

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- the proposed safeguards for the participants are well defined.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

- This is not an interventional study

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C1A – Both Children and Adults, Acceptable

- This is a study of minorities only. The decision to become an organ donor can only be made by those over 18 years of age in Alabama and therefore children <18 years of age cannot be included in this study.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Revision:

- As noted, this is a revised application and specific comments concerning previous reviews have been made.

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- This complies with NIH guidelines including all types of training materials.

Comments on Subject Matter (Required):

- Responsible conduct of research is appropriate

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- the applicant has outlined his own participation only which is appropriate

Comments on Duration (Required):

- appropriate duration during the entire proposed interval of support

Comments on Frequency (Required):

- appropriate

Budget and Period of Support:

Recommended as Requested

CRITIQUE 3:

Candidate:

Career Development Plan/Career Goals /Plan to Provide Mentoring:

Research Plan:

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Environment Commitment to the Candidate:

Overall Impact: The candidate is excellent and has a number of published papers, predominately on surgical- related issues. He is committed to increasing organ donation among African Americans and proposes a project on "Increasing African American Organ Donation: Donor Registration & Family Consent." He has put together an excellent team of committed mentors he is already working with. The environment is extremely supportive and conducive to his development as an independent investigator. Minor weaknesses include visits with 2 off-site mentors that are not accounted for in the budget, a distance from the actual collection of the data via focus groups and telephone interviews, and the lack of a timeline for publications associated with the project. Weaknesses in explanations of the mentors trainees and the training plan in the prior application have been well addressed. The research plan has been strengthened with the addition of some explanations requested for the methods, while the plan otherwise remains the same. Recruitment ability was a previous concern but the candidate has been able to recruit 87 African American volunteers from 6 counties for 6 focus groups for participation in a pilot project.

1. Candidate:

Strengths

- Derek DuBay is an Assistant Professor in the Transplant Surgery Dept at the Univ. of Alabama at Birmingham (since 2008). He received his MD degree from the Univ. of Iowa College of Medicine (1999), completed a General Surgery residency at U. Mich (2006), and a Transplant Fellowship at the Univ of Toronto (2008).
- He has a total of 28 publications (plus one recently submitted) since 2000 (19 as first author), and 4 (3 as fist author) in the year and a half since his original application (reviewed in March 2010).
- He is a member of the Ethics Committee for the American Society of Transplant Surgeons

Weaknesses

- For current support, he lists a 1-year pilot grant (10/2010 – 9/2011) from the Minority Health and Health Disparities Research Center at the Univ. of Alabama to study the Theory of Planned Behavior in order to determine what factors are important for becoming a registered organ

donor. This same grant was listed in the prior application but the dates and timing of funding are unclear since the dates listed now also show the grant as current.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Dr. DuBay plans to obtain an MSPH degree in Behavioral Science through the UAB SPH during this award. 41 credit hours are required for this degree. He will take full semesters of coursework over the first year, and then complete the coursework over the next two years. The core and proposed elective courses are highly relevant to the interests of the candidate and the proposed research project.
- The candidate will participate in a 1-year Health Disparities Training Program at UAB designed specifically for junior faculty. This includes such useful career development programs such as 5-day grant writing and manuscript writing retreats.
- In the early part of the award, he will attend a 4-day workshop retreat on conducting focus groups, which is critical for his proposed project. .
- Dr. DuBay is meeting approximately weekly with Dr. Redden, a PhD statistician to increase his skill and knowledge in the application of mixed model statistical methods techniques. This work is proposed to continue through the training program. Coursework in biostatistics toward his MSPH degree will also contribute to growing his strengths and knowledge in statistical analyses.

Weaknesses

- The candidate states that as he develops his statistical and programming skills with SAS, he will do more of his own statistical analyses/programming. Although helpful as a learning tool, the more fundamental goal is to be able to collaborate and communicate with a statistical colleague. This ability does not come without practice and ultimately will contribute to the candidate's long term productivity.
- The candidate proposes (and budgets for) attending only one scientific meeting during the course of the award to present results of his study. The candidate would benefit from annual attendance at one or two meetings for networking, collaboration and scientific exchange. He over-aggressively cut the excessive meeting travel requested in the prior application (4 meetings per year with no specific meetings mentioned)
- No timelines for the study, career development plan or for publications are provided.

3. Research Plan:

Strengths

- The overall aims from the original proposal remain the same: Aim 1 of this study is to characterize recent successfully registered African-American donors identified through the Alabama Department of Motorized Vehicles; and Aim 2 will be to see if these donors inform their families, and the determinants of doing so, since the ultimate decision lies with the next-of-kin.
- For Aim 1, influences on organ donation decision will be determined through 12 focus groups, with 10-15 participants each, half in rural and half in urban areas. 4 groups will include only those who elected to be donors, 4 only those who are not donor and 4 with a 50/50 mix of willing and non-willing donors. Questions regarding expectations about the consequences of registering to be a donor will be the emphasis of the focus group guided discussions.
- Focus group discussions will be transcribed and evaluated using a multi-functional software system for Transcribed focus group data and analyzed inductively in two stages using a qualitative data analysis software program, NVivo9.

- A telephone survey of n=500 African Americans (50% registered donors and 50% non-registered donors).

Weaknesses

- Beyond planning and analyzing, the candidate remains distanced from participation by not taking part in the focus groups and phone interviews, as was mentioned in review of the first submission. He states that his mentors suggest ‘...he should not personally conduct the focus groups, as this may introduce bias.’ However, it was not suggested that he conducts the focus groups, but that he observes at least some of them, with the trained facilitator conducting and the assistant recording them.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The primary mentor, Dr. Mona Fouad, is a faculty member in the UAB Division of Preventive Medicine with a primary research focus in health disparities and mentoring young minority investigators. She is the PI of the NCMHD-funded Comprehensive Minority and Health Disparities Research Center at UAB and co-investigator on multiple other health disparities focused grants. In the past 10 years, she has mentored 9 post-doctoral fellows or faculty members and 1 pre-doctoral trainee. All are either in training (3) or in academic or public health research positions. .
- The candidate will have monthly meeting with the full mentoring team, with the two off site (Holt and Siminoff) participating by phone. Dr. Hold has collaborated with Dr. Fouad for years. Dr. Siminoff is an expert in organ donation research.
- Meetings with mentors, including those off site, are well described and have been considerably strengthened since the previous application.

Weaknesses

- The candidate describes that he will meet annually with Drs. Holt and Siminoff at their respective academic institutions (U. Maryland, and Virginia Commonwealth Univ), but accommodations for this in the budget have been removed from the previous application. The investigator was asked to trim travel costs, but this particular piece should not be excluded.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- 75% protected time is endorsed by the Chairman of the UAB Department of Surgery. Surgeons are only required 50% of protected time, so this represents a major level of support for this candidate.
- Department of Surgery will match research funds of the grant with an additional \$ per year for research costs.
- Upon receiving a favorable score but unfunded award on his initial K23 application, his department began paying Dr. Redden for a % salary effort. Dr. Redden has a PhD in applied statistics and meets with Dr. DuBay weekly to discuss and work on analyses. The recently submitted manuscript with the candidate as first author includes Dr. Redden as second author.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Loss of confidentiality is the largest potential risk, but protections are discussed and will be in place. Participants will be paid \$100 for focus group participation and \$20 for telephone survey participation, which seems appropriate.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C1A – Both Children and Adults, Acceptable

- Both genders will be enrolled equally. The focus of the project is to increase organ donation among African American's, so this study is limited to this minority group. Legal adulthood is required to become an organ donor - age 19 and older is stated, but should that be 18 and older?

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Resubmission:

- See overall summary.

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- A 4 hour course provided at UAB for investigators, a 20 hour conference on Ethics by the UAB Center for Ethics, bioethics workshops offered by the UAB Minority Health and Health Disparities Center, and an Ethics and Values Conference offered by the UAB Center for Clinical and Translational Sciences will be completed by the candidate in addition to the standard online training.

Comments on Subject Matter (Required):

- Standard topics are included in the above listed courses and workshops: conflict of interest, authorship, peer review, mentor-mentee relationship, ethically managing data, the ethics of data gathering, human subjects, live vertebrate animal subject research, industry collaborations, misconduct, research fraud, and ethical issues in clinical trials.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Faculty participate in small group discussions in the UAB Center for Clinical and Translational Sciences Ethics and Values conferences.

Comments on Duration (Required):

- This is well described and ranges from 1 hour conferences to a 4 hour course to a 20 hour conference.

Comments on Frequency (Required):

- Each of the described courses or workshops will be taken once and the UAB Center for Clinical and Translational Sciences Ethics and Values conferences occur quarterly.

Budget and Period of Support:

Recommended budget modifications or possible overlap identified:

- Although the previous travel budget was too high, the revised budget does not allow for travel to meet with the two off-site mentors.
- The budget also now funds for the PI to attend only 1 scientific meeting to present study findings and results (with only 1 night at the meeting in the budget).

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

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

Only children 19-21 years old are included in the study.

SCIENTIFIC REVIEW OFFICER'S NOTES:

The plans outlined in the application to obtain training in the responsible conduct of research are adequate to satisfy this requirement.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Recommended direct cost levels are estimated and are subject to further adjustment based on the Institute's standard budget calculation practices.

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

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

MEETING ROSTER

**Kidney, Urologic and Hematologic Diseases D Subcommittee
National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
DDK-D 1
June 21, 2011 - June 23, 2011**

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