

# A pragmatic video intervention to promote African American organ donor registration at the Department of Motorized Vehicles

## Abstract

**Rationale:** There are 122,000 persons waiting for donor organs in the US, but only about 30,000 transplants are performed each year. The Department of Health and Human Services has set the goal that at least 50% of adults in each state become registered organ donors. Increasing donor registration is important with passage of first-person consent laws in all 50 states. First-person consent makes the indication of an adult's intent to donate organs (i.e. becoming a registered donor) legally binding, much like a living will. In Alabama, 77% of Caucasians are registered organ donors, but only 28% of African Americans are registered organ donors. There is need for persuasive educational interventions to increase African American organ donor registration.

**Objectives:** Over 97% of organ donor registrations (for all races) occur at the Department of Motorized Vehicles (DMV), making this the obvious intervention venue to increase donor registration. A series of studies of African Americans that recently visited a DMV in Alabama and made the decision (yes or no) to become a registered donor was conducted through the PIs current K23 Career Development Award. Most African American participants who decided not to become a registered donor stated they had not considered becoming a registered donor prior to being asked, and the safe answer was "no". To increase African American donor registration, participants advocated presenting organ donor information on flat screen TVs while standing in line at the DMV, and prioritized organ donor topics for the educational video. Building on these preliminary findings, the goal of the proposed study is to pilot a video intervention at the DMV to promote African American donor registration. The pilot project will be conducted during years 4 and 5 of the K23.

**Design and Methods:** The five Birmingham, Alabama area DMVs will be used for the pilot video intervention. Each DMV services a high proportion of African Americans. The Organ Donation Model will be used as the theoretical framework to help ensure that intervention is persuasive and effective. African American organ donor educational topics identified as most important through the PIs current K23 will be used to create a video storyboard. The video storyboard will be tested and modified based upon the results of audience research. A series of video narratives will be developed. The video narratives will then be further tested and modified with audience research. The final product will be a repeating 10-15 minute video intervention promoting the positive aspects of African American organ donor registration, presented via flat screen TVs to persons at the DMV. A randomized cross-over design using DMV facility as the unit of randomization will measure if the intervention increases African American donor registration when the video is playing compared to when the video is off.

**Significance:** The developed video content and efficacy data will serve the basis of a future R01 rolling out this intervention on a larger scale in the South. If effective, the DMV-based flat screen TV intervention may be utilized for other populations with low organ donor registration rates.

## **SPECIFIC AIMS**

There are 122,000 persons waiting for donor organs in the US, but only about 30,000 transplants are performed each year. The Department of Health and Human Services has set the goal that at least 50% of adults in each state are registered organ donors. Increasing donor registration is important with passage of first-person consent laws in all 50 states. First-person consent makes the indication of an adult's intent to donate organs (i.e., becoming a registered donor) legally binding, much like a living will. In Alabama, 77% of Caucasians are registered organ donors, but only 28% of African Americans are registered organ donors. There is need for persuasive educational interventions to increase African American organ donor registration.

Over 97% of organ donor registrations (for all races) occur at the Department of Motorized Vehicles (DMV), making this the obvious intervention venue to increase donor registration. A series of studies of African Americans that recently visited a DMV in Alabama and made the decision (yes or no) to become a registered donor was conducted through the PIs current K23 Career Development Award. Interestingly, most African American participants who decided not to become a registered donor stated they had not considered becoming a registered donor prior to being asked, and the safe answer was "no". To increase African American donor registration, participants advocated presenting organ donor information on flat screen televisions (TVs) while standing in line at the DMV. Participants recommended the most important organ donor educational topics (see preliminary studies) that may increase the frequency of African American organ donor registration.

Building on these preliminary findings, the goal of the proposed study is to pilot a video intervention at the DMV to promote African American organ donor registration (see DMV letter of support). The pilot project will be conducted during years 4 and 5 of the K23. Video will be developed that promotes organ donor topics identified to be important to African Americans via the PIs current K23. The video intervention will be presented using flat screen TVs at the DMV. Flat screen TVs are widely used in advertising today, and are most successful when the video promotion can be delivered at the point of decision-making (i.e. waiting in line at the DMV in the case of organ donor registration). Using flat screen TVs has upfront hardware and installation costs, but then has very low maintenance expenses. Thus this intervention can be sustainable over the long term and is easily modifiable. To help defray flat screen TV purchase and installation costs, the Alabama Organ Center has pledged \$25,000 for flat screen TV purchases, and has agreed to pay for flat screen TV maintenance fees at the conclusion of the study (see letter of support).

**AIM 1: Develop an educational video intervention promoting organ donation educational topics previously identified to be important to African Americans.** The organ donation model will be used as the theoretical framework to help ensure that the intervention is persuasive and effective. African American organ donor educational topics, identified through the PIs current K23 Career Development Award (see preliminary studies), will be used to create a video storyboard. The video storyboard will be tested and modified based upon feedback from the target audience. Partnering with a professional film company with experience in organ donation video production (see letter of support), a series of video narratives will be developed. The video narratives will be further tested and modified with additional audience research to ensure that it is appropriate for African Americans. The final product will be a repeating 10-15 minute video intervention promoting African American organ donor registration.

*Hypothesis.* A video educational intervention can be developed to promote key knowledge items that influence African American organ donor registration decisions at the DMV.

**AIM 2: Evaluate the efficacy of the DMV video intervention in increasing African American organ donor registration.** A large regional advertising company will be contracted to install and maintain the flat screen TVs (see letter of support). The DMV video intervention to increase organ donor registration will be piloted at the five Birmingham, Alabama DMVs, where over 50,000 African Americans obtained or renewed their driver's license in 2013. The video intervention will be administered using an interrupted time series design. The video will be on for 3 months, then off for 3 months. A randomized crossover design, where each DMV is randomized to an on/off sequence, will measure if the intervention increases African American donor registration when the video is playing compared to when the video is off. We currently track organ donor registration rates via a partnership with the Alabama DMV.

*Hypothesis.* African American organ donor registration will increase during the 6 months when the DMV video intervention is playing compared to the 6 months when the video is turned off.

**Expected Outcomes** The developed video content and efficacy data will serve as the basis for a future R01 rolling out this intervention on a larger scale in the South. Pending supportive outcome data, the DMV-based flat screen TV intervention may also be utilized for other populations with low organ donor registration rates.

## RESEARCH STRATEGY

### A. Significance

**A.1 Deceased Donor Organ Shortage.** There are 122,000 persons waiting for donor organs in the US as of 2014, but only around 30,000 transplants are performed each year.<sup>(1)</sup> On average, 18 people die each day from the lack of available organs.<sup>(1)</sup> The US Health and Human Services Department has set organ donation goals to address the shortage in transplantable organs.<sup>(2)</sup> Unfortunately, organ donation has experienced recent declines.<sup>(3)</sup> Examination of nationally available data suggests that organ donation goals are being met in Caucasians, but a large disparity in organ donation exists in African Americans.<sup>(3)</sup> One of the largest sources of unrealized potential organs is in African Americans. The odds of organ donor consent in Caucasians compared to African Americans is 4.67 in a recent study of potential donors in Alabama.<sup>(4)</sup>

### **A.2. There are well-established predictors for African American non-**

**donation.** Numerous studies document that African American race is a dominant predictor of non-donation.<sup>(5-7, 9, 19, 22-25)</sup>

Certain demographics, attitudes and beliefs are prevalent among African Americans unwilling to donate organs. (Table 1)

Mistrust of the medical system has been

demonstrated to be a dominant non-donation attitude,<sup>(17, 24, 25)</sup> especially in older African Americans.<sup>(9)</sup> Central to this concern is a fear that physicians will not do all they can to save the life of potential organ donors.<sup>(12, 17, 26)</sup>

**Table 1. African American Non-donation Predictors**

<b>Demographics</b>	<b>Attitudes and Beliefs</b>
Older Age <sup>(5-8)</sup>	Distrust of Medical System <sup>(9-15)</sup>
Male Gender <sup>(6, 16)</sup>	Distrust of Caucasians <sup>(6, 17, 18)</sup>
Low Education <sup>(8, 16)</sup>	Fear of Surgery <sup>(13, 17)</sup>
Unemployed <sup>(8, 19)</sup>	Fear of Disfigurement <sup>(16, 20)</sup>
Religious Beliefs <sup>(6, 9, 19)</sup>	Concern for Burial <sup>(13, 16-18)</sup>
	Unfamiliar with Donation <sup>(7, 20, 21)</sup>

### **A.3 The DMV is a feasible and efficacious site for increasing African American organ donor**

**registration.** Studies suggest that African Americans prefer to become registered organ donors at the DMV compared to other options.<sup>(27)</sup> Over 97% of all (both races) organ donor registrations in the state of Alabama take place at the DMV (~2.5% Internet and mail-in registration). Alabama residents are required to obtain/renew their driver's license every 4 years in-person at the DMV.

### **A.4 There has been 2 successful DMV-based interventions resulting in increased organ donor**

**registration.** Although there have not been previous DMV-based interventions targeted specifically to African Americans, there have been 2 very successful DMV-based interventions conducted by Harrison and Morgan.<sup>(28-30)</sup> These DMV-based interventions resulted in significant increases in organ donor registration (all races considered jointly). The earliest DMV intervention,<sup>(30)</sup> published in 2008, provided a 1-hour organ donation education session to DMV clerks in eight counties of a single state. Organ donor registration was 9-14% higher compared to non-intervention counties.<sup>(30)</sup> The second DMV intervention,<sup>(28, 29)</sup> first published in 2010, provided a multifaceted organ donation education approach consisting of a mass-media intervention (i.e., "media priming" achieved via radio ads and billboard advertising), point of decision-making materials (i.e., posters, foot prints, pamphlets), and on-site events (i.e., volunteers at the DMVs promoting donor registration). Compared to historic controls, this multifaceted organ donation promotion resulted in a 200-300% increase in organ donor registrations in 2 counties in Michigan compared to historic rates.<sup>(29)</sup>

### **A.5 There is need for sustainable DMV-based interventions that increase African American organ**

**donor registration.** The increased organ donor registrations observed in DMV-based interventions have been short lived, and the organ donor registration rates returned to baseline soon after the intervention ceased.<sup>(28, 29)</sup>

These DMV-based interventions also were resource intensive and too expensive to disseminate on a large scale, further limiting their reach. However, we currently live in an era of unprecedented technological capabilities with near unlimited electronic connectivity. Advertising companies have taken advantage of this technology by remotely advertising on flat screen TVs. Advertising on flat screen TVs is commonplace, being utilized in airports, public transit, hospitals, food courts, athletic games, gas stations, and elevators. Flat screen TVs are also used at DMVs to promote seat belt usage and to discourage drinking and driving, and texting and driving. Furthermore, brief educational video interventions have been proven to be effective in changing health behaviors. For example, an educational video promoting safe sex practices was displayed at 3 high volume sexually transmitted disease (STD) clinics in 3 large US cities. Incident STD infections (laboratory confirmed) were significantly decreased in participants exposed to the video during 15 months of follow-up.<sup>(31-33)</sup>

**Therefore, using flat screen TVs as a platform for an educational intervention is feasible and may be efficacious in increasing African American organ donor registration at DMVs.**

## B. Innovation

1. **Organ donor educational intervention delivered at point of decision-making.** Health interventions are most effective when the message is delivered around the point of decision-making.<sup>(34, 35)</sup> In the case of organ donor registration, the point of decision-making is at the DMV. In the PIs current K23 study of African Americans who recently visited a DMV and made a decision (yes or no) to become a registered donor, participants reported standing in line an average of 75 minutes, ample time to view the organ donor materials. The most common reason stated for not becoming a registered organ donor while at the DMV was simply that participants were unaware about, and had not considered, becoming a registered donor prior to being asked. The safe answer was “no” when queried by the DMV clerk. *We believe that a targeted organ donor educational message will increase African American organ donor registration at the DMV.*

2. **Easily measurable “hard” outcome.** The main outcome measure is African American organ donor registration rates. A comprehensive review of the factors influencing African American organ donation decisions was critical that most studies measured intention, and not actual organ donor registration rates.<sup>(36)</sup> We have an agreement with the Alabama DMV to provide the name, age, sex, address, DMV location, donor registration decision, and date of all African Americans who visit a DMV. We have obtained this data quarterly since 2013 and thus know the historical organ donor registration rates for all Alabama DMVs.

3. **Reproducible intervention.** Video content will be developed and displayed via flat screen TVs in the DMV. Participants will also have the option to send a text message to a number which will link them to the Alabama Organ Center website, enabling them to further investigate organ donation topics. This approach varies from two other known DMV-based organ donation interventions that relied upon on-site events,<sup>(28, 29)</sup> or educating the DMV clerk,<sup>(30)</sup> both of which are limited by human variation and ongoing staffing needs.

4. **Sustainable intervention.** The two previous DMV-based organ donation interventions<sup>(28-30)</sup> were very effective in increasing organ donor registration rates (across all races), but the effect rapidly disappeared after the intervention ceased. These interventions were also resource-intensive, both financially and from a human workload perspective. Using flat screen TVs has upfront hardware and installation costs, but then has very low maintenance expenses. Thus this intervention can be sustainable and easily modifiable. The Alabama Organ Center has an annual advertising budget of \$500,000. If all 97 DMVs in Alabama were outfitted with flat screen TVs, the yearly maintenance cost would be less than \$20,000, only 4% of the annual budget. *The flat screen TV organ donor education intervention will be a platform that can be used and re-used for many years.*

## C. Approach

We will develop and test an organ donor registration educational intervention delivered via flat screen TVs at the 5 Birmingham, Alabama DMVs. In 2013, there were over 50,000 organ donor registration decisions made by African Americans at these 5 DMVs. A multidisciplinary team of investigators from Clinical Transplantation, the UAB School of Public Health, and the UAB Minority Health and Health Disparities Research Center will conduct this study. The team has expertise in organ donation (DuBay), behavioral science and intervention evaluation (Martin), health communications utilizing electronic media (Schoenberger), and biostatistics (Redden).

**AIM 1: Develop an educational video intervention promoting organ donation educational topics identified to be important to African Americans.** A video storyboard (see below) will be created using the organ donation topics identified via formative research generated from the PI’s current K23 (Table 2). Partnering with a professional film company with experience in organ donation video production, a series of video narratives will then be developed culminating in approximately a 10-15-minute video intervention.

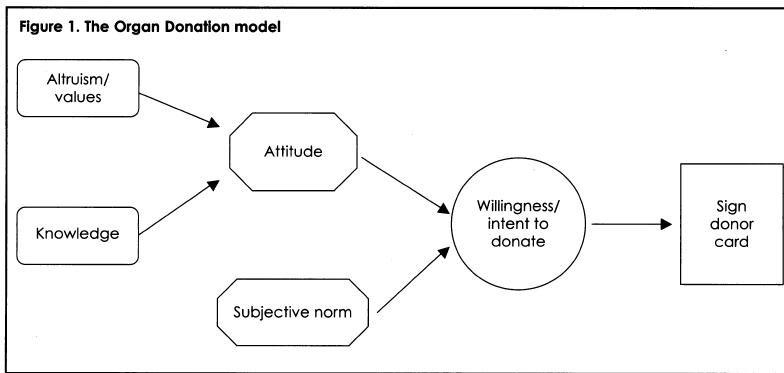
Theoretical Framework: The Organ Donation Model<sup>(37)</sup> will be used as the theoretical framework to help ensure that the organ donation flat screen TV educational intervention is persuasive and effective. The Organ Donation Model builds upon the Model of Factors Related to Organ Donation<sup>(38)</sup> and the Organ Donor Willingness Model<sup>(39)</sup>. The Organ Donation Model (Figure 1) posits that knowledge and attitudes combine with perceived social norms to influence decisions about organ donation.<sup>(37)</sup> The model is an adaptation of the Theory of Reasoned Action,<sup>(40)</sup> with additional emphasis on key knowledge items that influence decisions to

### Table 2. Organ Donor Educational Topics

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Medical Mistrust  
Need for Organs in African Americans  
Organ Donor Family Storytelling  
Transplant Recipient Storytelling  
What is Brain Death?  
Prevalent Organ Donation Myths  
Religious Groups Organ Donation Positions

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become a registered organ donor.<sup>(41, 42)</sup> The model has commonly been utilized in organ donor research, especially in African Americans<sup>(37)</sup> and also in DMV interventions to increase donor registration.<sup>(28, 30)</sup> As a result several studies have identified the key knowledge items<sup>(9, 10, 12, 20, 24, 26, 43)</sup> that distinguish African American donors from non-donors, best characterized as widely believed organ donation myths and fears.

(Figure 1 from Morgan SE, 2006<sup>(37)</sup>)

**Preliminary data:** The first phase of my research (pre-K23) was a study to measure attitudes, beliefs, barriers and facilitators associated with African American organ donor registration.<sup>(44)</sup> Participants identified family and friends, church, health care providers and community as exerting the most influence on their decision to become a registered organ donor. Information, and lack of information (related to organ donation) were the most common facilitators and barriers to making the decision to become a registered organ donor. (Table 3)

**This phase guides the content of the educational intervention.**

The second phase of my research (Aim #1 of K23) involved conducting 13 focus groups with African Americans age 19 and older who visited the DMV in the past 3 months and made a decision (yes or no) to become a registered organ donor. Registered organ donors (n=7 focus groups, n=52 participants) were compared to not registered organ donors (n=6 focus groups, n=48 participants). From this formative research, I developed a profile of the African American DMV audience by further exploring the concepts in Table 3,

identifying factors most influential to the decision of becoming a registered donor, and gauging the receptivity of a DMV-based intervention administered through different delivery channels. Participants recommended using flat screen TVs to deliver the educational video intervention. Altruistic approaches, storytelling (recipients and donor families), disseminating factual information, and debunking organ donor myths were emphasized as the most important factors influencing the decision to become a registered organ donor.

**This phase refines how the content is delivered and what themes are prioritized in the message (Table 2).**

**Table 3. Behavior: Becoming a Registered Organ Donor**

Behavioral Beliefs	Advantages	Altruism Making own decision
	Disadvantages	Fear Legal issues Organ usability
Subjective Norms	Approving	Family and friends Health care providers
	Disapproving	Family and friends Church/ Religious groups Community
Behavioral Control	Facilitators	Information Organ need in family Registration process in place
	Barriers	Lack of information Medical mistrust Fear

Adapted from Table 2 from DuBay et al 2014<sup>(44)</sup>

**Video Storyboard Development:** A video storyboard will be developed prior to any video creation. A video storyboard approach is commonly used for health behavior intervention development.<sup>(45-48)</sup> Using this approach provides a blueprint visual for potential consumers to view (like a comic strip). During the design process, ideas are generated and conveyed to “potential consumers” (via audience research) to evoke comments, judgment or acceptance<sup>(49)</sup>. Storyboards are a valuable aid to help formalize content prior to video creation.<sup>(49)</sup>

**Analysis phase:** The situation, interactions and context of the video’s intended use are considered.

**Synthesis phase:** A rough sketch of the product is created considering time elements.

**Simulation phase:** A working visual of the video intervention is developed, analogous to a carton strip. The storyboard evolves into a coherent narrative with a meaningful effective storyline.

**Evaluation phase:** Tentative storyboard designs are tested with “walk-throughs” accomplished via audience research. Salient suggestions will inform revisions to the storyboard which will be tested with additional audience research (see below) until no further significant suggestions/ concerns are raised by participants.

**Decision phase:** After the storyboard content and order are finalized, the visualization style is detailed to a photorealistic state and presented to the Alabama DMV and the Alabama Organ Center for approval.

**Audience research:** We will conduct audience research during the evaluation phase of video storyboard development to help inform the video storyboard development (n=6 groups, each with 6-8 participants). Participants will be African Americans ≥ 19 years old who visited the DMV within 3 previous months and chose to not become a registered donor. Participants will attend structured group interviews, similar to focus groups. Members will be asked to respond to the video storyboard content in a “round-robin” process with a brief group discussion of each set of responses. Participants will be probed to determine whether the information is clear, understandable, and personally relevant. Participants will be asked for their input regarding the tentative storyboard components including delivery format (still frame, story telling, etc.), target audiences (men/ women, young/ elderly), and who should deliver the different education topics (young, old, male, female, celebrity, health care provider, etc.). Participants will assess the readability of subtitles (created at a 6<sup>th</sup> grade reading level). Participants will be probed to determine which portions of the video storyboard captured their attention and may motivate them to become a registered organ donor. Responses will be analyzed to determine if the storyboard components are persuasive and potentially effective. The goal is to look for evidence of agreement or consensus among the group, and to identify the most ‘salient’ responses to guide decisions on how to modify the video storyboard. Salient responses are generally those that come up early (within the first several responses) and often.<sup>(50)</sup> Audience research will also be conducted on the created video (n=2 groups) for a preliminary evaluation of the persuasiveness and effectiveness of the video content.

Similar to the methods used in the PIs current K-award, participants will be recruited from 22 zip codes in and around Birmingham, Alabama. The audience research will be held on campus at UAB. Refreshments will be provided. Audio and video recordings of the audience research will be obtained. Participants will provide written informed consent prior to the start of the audience participation and complete a brief demographics questionnaire at the completion. Two experienced African American moderators from the UAB Health Disparities Research Center will conduct the audience research for elicitation consistency (same moderators utilized for K23 focus groups). Participants will receive monetary compensation (\$100) for travel and time required to participate in the audience research. We have an effective mechanism in place to identify and recruit these persons. The Alabama DMV provides a quarterly list of African Americans who recently visited the DMV and decided (yes or no) to become a registered organ donor. A postcard is sent inviting these persons to participate in our study. Our response rate has exceeded available spots (194 persons recruited for K23).

**Video production:** The video production will be performed by a professional film company who currently produces organ donation video content for the Alabama Organ Center (see letter of support). Actual African American organ donor families and transplant recipients from Alabama will be used for video creation.

**Expected Outcomes.** The final product will be a repeating approximately 10-15 minute education video intervention promoting African American organ donor registration that is both persuasive and effective.

**Potential Limitations and Alternative Approaches.** A limitation to this intervention is the assumption that DMV patrons will actually watch the video, and that a 10-15 minute educational video will be persuasive for DMV patrons to become registered organ donors. Another limitation is ensuring created video targets African Americans, but is not interpreted as “overly directive”. Our approach to these potential limitations is to use audience participation research for video storyboard development to verify the video is both persuasive and appropriate for an African American DMV audience.

**AIM 2: Evaluate the efficacy of the DMV video intervention in increasing African American organ donor registration.** The DMV video intervention to increase organ donor registration will be piloted at the five Birmingham, Alabama DMVs, where over 50,000 African Americans obtained or renewed their driver’s license in 2013. The video intervention will be administered using an interrupted time series design, an approach recommended for media interventions.<sup>(51, 52)</sup> The video will be on for 3 months, then off for 3 months. A randomized crossover design, where each DMV is randomized to an on/off sequence, will measure if the intervention increases African American donor registration when the video is playing compared to when the video is off. We currently track organ donor registration rates via a partnership with the Alabama (Table 4).

***Hypothesis.*** African American organ donor registration will increase during the 6 months when the DMV video intervention is playing compared to the 6 months when the video is turned off.

**Flat screen TV installation and maintenance:** A local advertising company (Highlands Digital Video) will be used to install and maintain the flat screen TVs. After review of the five proposed intervention DMVs, the company has recommended installing 2 flat screen TVs for the sitting area (DMV patrons are given a number when they check in and directed to a sitting area) and an additional flat screen TV in the line leading up to the DMV clerk. The flat screen TVs are 40 inches in size and of commercial grade construction designed for public use. The Alabama Organ Center has pledged \$25,000 to help defray flat screen TV purchase and installations costs. At the conclusion of the study, the Alabama Organ Center has agreed to pay for TV maintenance fees.

**Power Analysis:** Logistic regression will be the primary analytic approach to examine the associations between becoming a registered organ donor and exposure to the video intervention. Assuming a two-tailed Type I error rate of .05 and a dichotomous risk factor with prevalence of 0.5 (justified by observing half the total sample exposed to the intervention and half the sample not exposed to the intervention), then a sample size of 2,000 individuals, all of whom have never consented to organ donation) provides 80% power to detect an odds ratio of 1.333. This calculation assumes that the pre-intervention probability of organ donation consent is 0.275 and the post-intervention probability is 0.336. This effect size implies that the odds of the individual becoming a registered organ donor in the periods when the screens are broadcasting the intervention are 1.33 times the odds of a person becoming a registered organ donor in the periods when the screens are not broadcasting.

There are over 850 African Americans who visit each of the five intervention DMVs each month and make a decision yes or no to become a registered donor so a sample size of 2,000 African Americans is achievable.

**Table 4. African American organ donor registration rates in past 12 months**

	5 Birmingham DMVs	Remainder of Alabama
Total Sample Size	51,543	231,349
Gender		
Female (%)	54.5%	56.1%
Male (%)	45.5%	43.9%
Age ± (Mean SD)	39.8 ± 17.2	38.4 ± 17.3
YES Organ Donor Registration		
Age 19-30 (% Female)/(% Male)	36.4% // 29.3%	38.5% // 32.4%
Age 31-50 (% Female)/(% Male)	36.2% // 30.1%	34.2% // 29.3%
Age >51 (% Female)/(% Male)	21.9% // 21.2%	19.5% // 21.0%

**Statistical Analysis:** Demographic information will be summarized using measures of central tendency and dispersion. Each of the DMV sites can be considered a cluster and may generate an intraclass correlation among individuals. There are multiple approaches that can be utilized to address this issue including fixed effects logistic regression (where each separate cluster is represented by indicator variables), generalized estimating equations, or generalized linear mixed models. Issues of applying generalized estimating equations and generalized mixed linear models, especially with regard to Type I error rates, are well documented especially when a small number of clusters is used (less than 40 clusters). Therefore we will analyze the data using fixed effects logistic regression. Crude associations between intervention period and registration will be tested using Cochran Mantel Haenszel Tests where DMV site is used as a stratification variable. Effects will be summarized using 95% Confidence Intervals for Odds Ratios. To account for the cross-over design, multivariable logistic regression models will be used to first test for carry-over effects by examining the interaction between intervention and time. Carry-over effects are not anticipated due to the nature of the intervention. After testing for carry-over effects, multivariable logistic regression will be used to estimate intervention effects after controlling for demographics.

**Expected Outcomes.** The cluster design randomized control trial will measure the efficacy of the DMV-based organ donation TV flat screen educational intervention in increasing African American organ donor registration.

**Potential Limitations and Alternative Approaches.** The average wait time at the DMV is 75 minutes, thus a patron may see the full video 5+ times, and we question if this will be irritating. DMV patrons will be encouraged to text DONOR to a phone number, after which they will receive an auto-response message with a link to the Alabama Organ Center’s website, where they can access in-depth organ donor educational items on their smart phones (including audio if the patron has audio ‘ear buds’).

**Significance.** The strengths of this study are that actual organ donor registration rates, not intentions, are measured and that this intervention has the opportunity to reach over 50,000 African American participants. The developed video content and efficacy data will serve as the basis of a future R01 project that will roll out this intervention on a larger scale throughout the South. Pending supportive outcome data, the DMV-based flat screen TV intervention may also be utilized for other populations with low organ donor registration rates.

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**SUMMARY STATEMENT**  
( Privileged Communication )

*Release Date:* 04/14/2015

**PROGRAM CONTACT:**  
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*Application Number:* 1 R03 DK106432-01

**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:* 03/03/2015  
*Council:* MAY 2015  
*Requested Start:* 07/01/2015

*RFA/PA:* PAR12-285  
*PCC:* KTR KTR

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***Project Title:*** A pragmatic video intervention to promote African American organ donor registration at the Department of Motorized Vehicles

***SRG Action:*** Impact Score:

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

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

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

***Gender:*** 1A-Both genders, scientifically acceptable

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

***Children:*** 1A-Both Children and Adults, scientifically acceptable  
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1		
2		
<hr/>		
TOTAL		

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

**RESUME AND SUMMARY OF DISCUSSION:** This application was submitted in response to program announcement PAR12-285 entitled “Limited Competition: Small Grant Program for NIDDK K01/K08/K23 Recipients (R03)”. The goal of the proposed study is to pilot a video intervention at the Department of Motorized Vehicles to promote African American donor registration. The outlined studies address a significant problem of low organ donation rates among this group. The proposed approach is innovative; feasible; and supported by adequate preliminary data and necessary resources. Strengths of the application include the Principal Investigator, who has made outstanding progress in research and training goals of the K23 award and is successfully transitioning to independence by developing a strong independent research program. The academic environment and support of collaborators are outstanding. Overall, this is a high impact, exceptional application.

**DESCRIPTION (provided by applicant):** A pragmatic video intervention to promote African American organ donor registration at the Department of Motorized Vehicles Abstract Rationale: There are 122,000 persons waiting for donor organs in the US, but only about 30,000 transplants are performed each year. The Department of Health and Human Services has set the goal that at least 50% of adults in each state become registered organ donors. Increasing donor registration is important with passage of first-person consent laws in all 50 states. First-person consent makes the indication of an adult’s intent to donate organs (i.e. becoming a registered donor) legally binding, much like a living will. In Alabama, 77% of Caucasians are registered organ donors, but only 28% of African Americans are registered organ donors. There is need for persuasive educational interventions to increase African American organ donor registration. Objectives: Over 97% of organ donor registrations (for all races) occur at the Department of Motorized Vehicles (DMV), making this the obvious intervention venue to increase donor registration. A series of studies of African Americans that recently visited a DMV in Alabama and made the decision (yes or no) to become a registered donor was conducted through the PIs current K23 Career Development Award. Most African American participants who decided not to become a registered donor stated they had not considered becoming a registered donor prior to being asked, and the safe answer was “no”. To increase African American donor registration, participants advocated presenting organ donor information on flat screen TVs while standing in line at the DMV, and prioritized organ donor topics for the educational video. Building on these preliminary findings, the goal of the proposed study is to pilot a video intervention at the DMV to promote African American donor registration. The pilot project will be conducted during years 4 and 5 of the K23. Design and Methods: The five Birmingham, Alabama area DMVs will be used for the pilot video intervention. Each DMV services a high proportion of African Americans. The Organ Donation Model will be used as the theoretical framework to help ensure that intervention is persuasive and effective. African American organ donor educational topics identified as most important through the PIs current K23 will be used to create a video storyboard. The video storyboard will be tested and modified based upon the results of audience research. A series of video narratives will be developed. The video narratives will then be further tested and modified with audience research. The final product will be a repeating 10-15 minute video intervention promoting the positive aspects of African American organ donor registration, presented via flat screen TVs to persons at the DMV. A randomized cross-over design using DMV facility as the unit of randomization will measure if the intervention increases African American donor registration when the video is playing compared to when the video is off. Significance: The developed video content and efficacy data will serve the basis of a future R01 rolling out this intervention on a larger scale in the South. If effective, the DMV-based flat screen TV intervention may be utilized for other populations with low organ donor registration rates.

**PUBLIC HEALTH RELEVANCE:** A flat screen video educational intervention to increase organ donor registration will be piloted at the five Birmingham, Alabama Department of Motorized Vehicle facilities. The video intervention will be administered using an interrupted time series approach with a randomized crossover trial design to measure if the video intervention increases African American organ donor registration.

## **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:**

Significance:

Investigator(s):

Innovation:

Approach:

Environment:

**Overall Impact:** The proposed R03 is from an investigator who has made significant progress on his K-award over 2.5 years, with numerous related publications. The concept of increasing donation registration among African Americans through a video shown in DMVs builds on work done as part of the K award. The environment is wholly supportive and the investigators are well suited for making the proposed research a success. There is a high need for increasing organ availability. The approach is reasonable and doable within the proposed timeline. The work is likely to provide a foundation for future funding and independence for the candidate, in addition to increasing donor registration among African Americans - and ultimately multiply organs available for those awaiting transplant.

#### **1. Significance:**

##### **Strengths**

- Overall there is an organ shortage and organ donation registration and donations are particularly low in African American community. The difference in the rate of those going on the waiting list to and available organs continues to widen at an alarming rate, according to the US Department of Health and Human Services.
- An effective and sustainable intervention could have a high impact on organ donor registrations and will likely lead to evaluation of this type of intervention in other locations and populations.
- The proposed intervention is a direct expansion of the work on the K award and is likely to contribute to more independent and focused work in this area by the investigator. This work is completely independent from the work of his mentors on his current K-award.
- Other investigators have shown success interventions at DMVs for increasing organ donation registration, but one intervention educated DMV clerks and another was a multi-media program. Both were effective, but expensive or otherwise not sustainable.

##### **Weaknesses**

- Generalizability of the intervention may be difficult. Although this is acknowledged, so an idea of the work involved to move this into a larger trial in different communities is needed.

#### **2. Investigator(s):**

##### **Strengths**

- This study is a natural extension of the work that Dr. DuBay has already done as part of his K and he is well prepared to plan and implement this study, as well as to publish the results. The

results are likely to lead to additional funding for expansion of this intervention into other communities and for broader and more general use.

- Dr. Michelle Martin has a PhD in Clinical Psychology and will devote 10% effort to this project. She has expertise in development of theory based interventions and how they impact behavior change. She is well suited for the needs of this project and she has been a mentor and co-author with the PI on 2 manuscripts from his K-award.
- Dr. David Redden has a PhD in Applied Statistics and has been a part of the PI's K-award research and publications. He is well suited for providing statistical oversight and collaboration for this project.

### **Weaknesses**

- Dr. Schoenberger is noted to have expertise in health communications utilizing electronic media and is described as being critical to the project. Her time will be covered from what is already being paid by the K-award funds. No Biosketch is provided and her current role on the K-award is not described.
- Dr. Fouad is the primary mentor for the applicant's K-award and her Biosketch is included. There is no role noted for her on this project.

### **3. Innovation:**

#### **Strengths**

- The idea is novel in that it puts forth a potential cost-effective method for positively impacting donor registration among African Americans.
- The plan extends the work and does not diverge from the original plan, which has been to understand barriers to organ donation registration toward increasing registrants and ultimately making more organs available for donation.

#### **Weaknesses**

- None noted.

### **4. Approach:**

#### **Strengths**

- There are 2 Aims – First to develop an educational video promoting organ donation among African Americans that will be informed from work done in focus groups for the K-award.
- Aim 2 will evaluate the use of the video in increasing AA organ donor registration at the DMV. All 5 Birmingham DMVs will have equipment installed (industrial flat screen TVs) to show the video (10-15 minute repeating loop; DMVs randomized to 3 month cross-over).
- The video will be produced using a private company that already produces an organ donation video for the Alabama Organ Center. African American organ donor families and recipients will be in the video.
- Over 50,000 AAs renewed or obtained driver's licenses in 2013, and known estimates show that 19 to 38% agree to be registered as donors currently, which varies by age group and by gender. An overall rate of approximately 27.5% is provided. Power estimates show the ability to detect a minimum increase in donation registration of 33%.

#### **Weaknesses**

- Evaluation of increases by certain age groups and by gender are not described; it may help to better target future videos to enhance donation in groups since there is a good amount of variation by these demographics.

## **5. Environment:**

### **Strengths**

- This project has letters showing full support from UAB, the local Department of Motor Vehicles and Department of Public Safety, the Alabama Organ Center, a media company for installation and maintenance of the televisions to be used in the DMV, and a freelance video production company. The resources needed are all in place and this is likely to be a successful endeavor given the stated commitment of each entity.

### **Weaknesses**

- None noted.

## **Progress on the K Career Development Award:**

### **Comments**

- Dr. DuBay is a transplant surgeon whos K award began in 2012 and is titled 'Improving African American Organ Donation: Donor Registration and Family Consent'. He has 6 publications related to Aim 1 of the K-award, which is focused on understanding factors that motivate African Americans to become registered organ donors through the DMV (5 as 1st author, 1 as senior author). Information for these manuscripts was derived from completion of 13 focus groups, including a total of 100 participants.
- Aim 2 of his K-award was to evaluate determinants of having registered AA donors convey their desire to donate to their family. The focus group process for this aim is underway. As a second part of this Aim, telephone interviews will validate findings.
- He has been a co-author on 6 additional papers centered on liver transplantation, but not directly related to his K-award.
- The candidate has made steady progress on his MSPH degree and is on target to complete the degree in the planned timeframe.
- Overall, the K-award research project is on target with respect to the planned timeline, with a successful track record of publishing.

## **Protections for Human Subjects:**

### **Acceptable Risks and/or Adequate Protections**

- Privacy and potential discomfort of hearing about death and organ donation are the only risks. Adequate protections are in place for protection of privacy. Consent will be waived for viewing the video

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

### **Inclusion of Women, Minorities and Children**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

- All self-identified African American's of approximately male/female distribution will be included. Only legal adults can register as organ donors so those 19 and older will be included. Why not 18 and older?

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resource Sharing Plans:**

Acceptable

- The produced video will be available for anyone to view/use on the Alabama Organ site.

**Budget and Period of Support:**

Recommended budget modifications or possible overlap identified:

- Support for Dr. Schoenberger should be evaluated for some level of support from this grant.

**Additional Comments to Applicant (Optional):**

**CRITIQUE 2:**

Significance:

Investigator(s):

Innovation:

Approach:

Environment:

**Overall Impact:** This is an R03 proposal from a transplant surgeon addressing disparities in organ transplantation. The candidate has been productive in his K23 award, and this proposal has developed out of the candidate's current K23 award, in which he has used qualitative research methods to assess and define barriers to organ donation in AA's. In his K23 award research, the candidate found that most African American participants who decided not to become a registered donor at the DMV stated they had not considered becoming a registered donor prior to being asked. He is therefore proposing to pilot a video intervention at the DMV to promote African American organ donor registration. The project is innovative, and collaborative outside of the clinical setting.

**1. Significance:**

**Strengths**

- Goal is to produce and evaluate the efficacy of a video intervention to promote organ donation in AA's
- This is an important area of study as many AA wait for organs

**Weaknesses**

- Impact of increased donation on overall donor shortage and long waiting list may still be small

**2. Investigator(s):**

**Strengths**

- A transplant surgeon, interested in health communication and behavior
- Currently obtaining a MSPH



- 41 peer-reviewed publications; 15 in past three years
- Has been productive on his K award

**Weaknesses**

- None noted

**3. Innovation:**

**Strengths**

- The proposal is innovative
- DMV as a site for the intervention is clever as in Alabama individuals must renew driver's licenses in person at the DMV every 4 years
- Rationale of intervening at the point of decision making is also compelling, and a successful intervention would be relatively easy to modify, sustain and expand to other sites

**Weaknesses**

- Not clear what impact of increasing organ donation consent rates ultimately would have on transplant rates

**4. Approach:**

**Strengths**

- Candidate cites prior DMV based interventions that increased organ donation
- Builds logically from findings from K23 about areas that would be important to focus on in these video interventions
- Content, structure of video will be vetted by participants recruited from 22 zip codes in and around Birmingham, Alabama.
- Sound design: the video intervention will be administered using an interrupted time series-on for 3 months, then off for 3 months. A randomized crossover design, where each DMV is randomized to an on/off sequence, will measure if the intervention increases African American donor registration when the video is playing compared to when the video is off

**Weaknesses**

- It is not completely clear to this reviewer how the candidate will know if these are NEW organ donors, or individuals who were previously organ donors

**5. Environment:**

**Strengths**

- Has letters of collaboration from the DMV, video maker, and flat screen providers- unusual and innovative approach
- Promoted already to Associate Professor
- Very busy transplant program, high proportion of URM candidates for transplantation

**Weaknesses**

- None noted

**Progress on the K Career Development Award:**

Comments

- Has made significant progress on the K, 5 published MS and one under review

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- Justifies that it is necessary to be 19 to be an organ donor in Alabama

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Resource Sharing Plans:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 3:**

Significance:

Investigator(s):

Innovation:

Approach:

Environment:

**Overall Impact:** Dr. DuBay is a transplant surgeon at UAB whose K23 application centers on understanding the barriers and facilitators of organ donor registration among African Americans in Alabama. He has made excellent progress on his K23 and is on target to complete the projects and training within the award period. This application is to support a pilot video intervention at the DMV to promote organ donation by African Americans. The intervention will be developed based on results obtained during the parent K23 studies. The problem of low organ donation rates among African Americans is important, and this study has the potential to effectively address it.

**1. Significance:**

**Strengths**

- Increasing organ donation is necessary to increase transplantation, a key goal of HHS's Healthy People initiative. African Americans have much lower rates of donor registration in Alabama than Caucasians despite the higher burden of ESRD among African Americans.
- An intervention delivered at the point of decision with input from the target audience has high potential to increase donation registration.
- This intervention has the potential to be scalable and sustainable with support from the Alabama Organ Center and the DMV.

### **Weaknesses**

- None noted

### **2. Investigator(s):**

#### **Strengths**

- Dr. DuBay is a transplant surgeon at UAB who was promoted to Associate Professor with Tenure in 2013.
- During his K23, Dr. DuBay has published six papers related to kidney transplantation, five of which are first author, as well as six other publications, mainly as first or last authored.
- Dr. DuBay's team of mentors and co-investigators provide expertise in organ donation, behavioral science and intervention evaluation, health communications using electronic media, and biostatistics.

#### **Weaknesses**

- There is no Biosketch or letter of support from Dr. Schoenberger, although her effort will be supported through the K23 application, and she appears to work closely with Dr. Martin.

### **3. Innovation:**

#### **Strengths**

- Dr. DuBay has put together an innovative proposal that utilizes the multidisciplinary team of collaborators he has assembled to develop and implement an intervention that will use information gathered from his K23-supported research to try to increase registration for organ donation among African Americans at the DMV.

#### **Weaknesses**

- None noted

### **4. Approach:**

#### **Strengths**

- The intervention will build very nicely on the work Dr. DuBay has done during the period of K23 support.
- Delivery of the intervention at the DMV where potential donors make the decision whether to register is a strength.
- The interrupted time series design with random order of intervention and control periods is appropriate to test the hypothesis.
- The outcome of actual registration rather than intent to register is a strength.

#### **Weaknesses**

- The hypothesis for Aim 2 does not match the approach, mentioning six-month intervention and control periods vs. 3-month periods.

### **5. Environment:**

#### **Strengths**

- The environment is extremely well suited to the study. Alabama appears to have a particularly large population of African Americans not registering to be organ donors. Dr. DuBay's team of mentors and collaborators are talented and supportive of him. He has forged important

partnerships with the Alabama Organ Center and the DMV, and has identified industry support for the production and deployment of the interventions.

**Weaknesses**

- None identified.

**Progress on the K Career Development Award:**

- The applicant has made excellent progress on the research and training goals of the K23. He has published some of his results and is on track to complete the work within the period of support.

**Protections for Human Subjects:**

Acceptable Risks and/or Adequate Protections

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

Unacceptable

- No Data and Safety Monitoring Plan included, although risk is minimal

**Inclusion of Women, Minorities and Children:**

G1A - Both Genders, Acceptable

M2A - Only Minority, Acceptable

C1A - Children and Adults, Acceptable

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Resource Sharing Plans:**

Acceptable

**Budget and Period of Support:**

Recommend as Requested

**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWER'S WRITTEN CRITIQUES, 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 will be included

**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.

14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer\\_review\\_process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).

## MEETING ROSTER

**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**

**March 03, 2015 - March 05, 2015**

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