

The Impact of Ethnicity on Research Authorization at the Time of Organ Donation: A Single-Center Experience Among Deceased Donor Kidney Transplantation

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ABSTRACT

Objective: Research on deceased organ donors is needed to expand the donor organ supply. Little is known about the rate of research authorization among various groups. We aimed to determine the percentage of research authorization by the deceased donor family across different donor characteristics.

Methods: We performed a retrospective review of deceased donors referred to 1 United States institution for kidney transplantation over a 12-month period. Organs were offered from multiple organ procurement organizations (OPOs) across the United States. Stepwise logistic regression was performed to determine the predictors of research authorization.

Results: From October 2018 to October 2019, 437 deceased donors were accepted for transplantation. About 81.5% came from OPOs outside our donor service area and 18.5% from our local OPO. Overall, research authorization was declined in 24.0% of donors. Declined authorization was highest among Black donors (42.0%) compared to Whites (16.3%) and Hispanics (26.9%) ($P = .000006$). Donors <35 years had the highest declined research authorization at 42.9% compared to older donors. There were no significant differences between individual OPOs.

Conclusion: Deceased donor research authorization declined at the time of organ donation is higher among Black and younger donors. There is an immediate need for the transplant and donor community to develop best practices to eliminate barriers to research in organ transplantation.

Keywords: Deceased donor kidney transplantation, disparities in organ donation authorization, next-of-kin authorization, renal transplantation, research authorization

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INTRODUCTION

Research on deceased donors plays a cardinal role in expanding our understanding of factors that influence the quality and quantity of organs for transplantation. With the growing waiting list, the pool of available deceased donor organs does not meet the demand, resulting in deaths on the waiting list each year. To improve the opportunity for transplantation, allocation schemes have attempted to optimize the pool of available donors. In kidneys, the use of expanded criteria organ donors and donation after circulatory death have been implemented in standard clinical practice.¹

Research on organ donors continues to be performed in an attempt to expand the donor organ supply. This includes the use of donor management protocols that increase both the quantity and quality of organs²⁻⁴ and also the function of organs from brain-dead donors, such as systemic donor cooling³ and external machine perfusion.^{5,6} However, in each of these organ donor studies, donor families must authorize participation in those research protocols – without the donor family's research authorization, those donor organs cannot be included for research purposes. This includes the 2 recently begun natural history studies HOPE in Action⁷



and the APOLLO Network,⁸ which are evaluating the safety of transplanting human immunodeficiency virus (HIV)-positive donor kidneys into HIV-positive recipients and the impact of *APOL1* genetic variants in deceased donors, respectively.

While such research allows new insights and opportunities to expand the pool of transplantable deceased donor organs, donor-oriented research faces many regulatory, ethical, and logical barriers to being successfully implemented.^{3,9-12} The Uniform Anatomical Gift Act (UAGA)¹³ is a statutory law that governs any research on deceased donor body or organs post-mortem. As per UAGA, when an adult decides to donate their organs after death, it can be used for any of the 3 permitted purposes (transplantation, research, or education). Each state dictates its own donor registry, where the purpose may be transplantation alone or may include education and research. In situations where the donor registry does not include authorization for research, then the deceased donor families would be the decision-makers. According to many state laws, the family member or next of kin (NOK) cannot override the decision of the registered donor at the time of death; however, there is a lack of consensus and regulatory ambiguity between different organ procurement organizations (OPOs) in this regard. The intervention of interest must comply with the ethical committee decisions of both donor and recipient hospitals and should not compromise the organs donated for transplantation, which may go against the wishes of donors and donor families.^{12,13}

Kidney donor profile index (KDPI) is a calculation utilized for the allocation of deceased donor kidneys in the USA. Kidney donor profile index includes 10 donor variables, including race. According to the KDPI imputation, kidney allografts transplanted from Black donors have roughly a 20% higher graft loss rate compared to other non-Black donors.¹⁴ This disparity in outcome stresses the importance of research involving organs from Black donors. There is an existing disparity between different ethnic/racial groups with regard to organ donation authorization.¹⁵ There is likewise a disparity in clinical research participation based on ethnic/racial groups.¹⁶ There are many factors that contribute to these differences such as language barriers, cultural/religious beliefs, and, in certain ethnic groups, distrust in “medical research.”¹⁷ At the time of approach for consent,

ethnic differences between the requestor and the donor family and the misinterpretation of research intent by the donor family could all be obstacles to NOK research consent.

To explore these disparities further, we performed a retrospective analysis among deceased donor kidney transplants referred to our institution. Our aim was to determine the percentage of research authorization by deceased donor families among different racial/ethnic groups and to investigate the joint impact of this association along with donor age, donor gender, and OPO origin of the organs.

METHODS

We obtained our data through a retrospective review of the electronic records from the United Network for Organ Sharing (UNOS) and their secured, password-protected transplant application, DonorNet, which houses all transplant-related information, including demographics and organ donation authorization. Based on the US Department of Health and Human Services, Common Rule [45 Code for Federal Regulation (CFR) Part 46], this review of de-identified records related to deceased individuals who did not meet criteria for human subjects research, and neither Institutional Review Board approval nor informed consent was required. We reviewed records of all deceased donors who consented for organ donation that were referred to our institution for kidney transplantation from multiple OPOs across the USA, during a 12-month period, from October 28, 2018 to October 31, 2019. This work was conducted prior to the change in the organ allocation scheme on March 15, 2021. The outcome of interest for the study was the presence of NOK or first-person authorization (FPA) for deceased donor research procedures, such as donor interventions or specimen collections. The organ donation and research authorization forms were obtained from DonorNet; we reviewed the forms related to NOK either allowing or declining research. In the case of registered donors or FPA, we verified each official state form to include research and education in addition to the NOK forms either declining or allowing research. Each donor was counted once (i.e., the sample size represented the total number of distinct donors) regardless of the number of organs (kidneys) donated. Donor characteristics, including age, gender, and race/ethnicity were extracted from DonorNet. The ethnicity/race categories were based on UNOS definitions. Donor race/ethnicity was recorded by the OPO coordinator at the donor hospital, who interviewed the deceased donor’s NOK and is considered as “self-reported.” We separated the groups into White (non-Hispanic), Black (non-Hispanic), Hispanic, and Asian.

The primary objective was to determine whether there were any significant differences in research authorization by the NOK among the different donor racial/ethnic groups. We also considered the potential impact of donor age, donor gender, and OPO of origin on the likelihood of research authorization by the NOK. The primary OPO serving our donor service area (DSA), Life Alliance Organ Recovery Agency, is considered our “local”

MAIN POINTS

- This study was a retrospective review at a single United States transplant center over a 12-month period.
- Research authorization within the organ donation consent form by the next of kin was reviewed.
- Declined rates of authorization were higher, almost 3-fold, among black donors compared to White and Hispanics and among younger donors, under the age of 35.
- There is an immediate need for the transplant and donor community to develop best practices to eliminate barriers to research in organ transplantation.

OPO. Organ procurement organizations from outside our DSA providing kidney offers were considered as “imported.”

Distributions of donor characteristics were summarized using arithmetic means and corresponding standard errors (along with medians and interquartile ranges) for continuous variables and percentages with the characteristics for categorical variables. Tests of associations were performed using the standard *t*-tests (or analysis of variance *F* tests) for continuous variables and Pearson chi-square tests for categorical variables. Stepwise logistic regression was performed to determine the significant multivariable (independent) predictors of research authorization being granted by the donor family. In the attempt to avoid reporting any spurious associations, a type I error of 0.01 was used. Cross-tabulations were generated based on the stepwise logistic regression results. Statistical analysis was performed using SAS 9.4 for Windows (SAS, Inc. Cary, North Carolina, USA).

RESULTS

During the 12-month study period, a total of 437 kidney donor offers to our institution were accepted for transplantation. The distribution of donor characteristics is shown in Table 1. The mean donor age was 45.4 ± 0.7 years. The percentages of donors <35, 35-49, and ≥50 years of age were 27.2% (119/437), 26.5% (116/437), and 46.2% (202/437), respectively. The majority of donors were male 60.9% (266/437). The distribution of deceased

Table 1. Distribution of Baseline Variables (N = 437)^a

Baseline Variable	Mean ± SE (and Median Along with Interquartile Range) If Continuous; Percentage with Characteristic If Categorical
Donor age (years)	45.4 ± 0.7 48.0 (34-57)
Donor age group	
< 35 years	27.2% (119/437)
35-49 years	26.5% (116/437)
≥ 50 years	46.2% (202/437)
Race/ethnicity	
White	59.0% (258/437)
Black	22.9% (100/437)
Hispanic	17.8% (78/437)
Asian	0.2% (1/437)
Donor gender	
Female	39.1% (171/437)
Male	60.9% (266/437)
Donor origin	
Local	18.5% (81/437)
Imported	81.5% (356/437)

^aEach donor was counted once, regardless of the number of deceased donor kidneys donated.

Table 2. Percentage of Donor Families Declining Research Authorization by Donor Race/Ethnicity

Donor Race/Ethnicity	Donor Family Research Authorization, % (n)		P ^a
	Declined	Approved	
White	16.3 (42/258)	83.7 (216/258)	.000006
Black	42.0 (42/100)	58.0 (58/100)	
Hispanic	26.9 (21/78)	73.1 (57/78)	
Asian	0.0 (0/1)	100.0 (1/1)	

^aPearson (uncorrected) chi-squared test with 3 degrees of freedom.

donors by race/ethnicity was as follows: White, 59.0% (258/437); Black, 22.9% (100/437); Hispanic, 17.8% (78/437); and Asian, 0.2% (1/437). Of the 437 deceased donors, 81.5% (356/437) came from OPOs outside our DSA, which included 51 different OPOs across the USA (“imported”). The remaining 18.5% (81/437) of deceased donors came from our “local” OPO (Table 1).

Overall, research authorization was declined in 24.0% (105/437) of donor organs offered. Declined authorization was higher among Black donors 42.0% (42/100), whereas declined authorization was 16.3% (42/258) among White donors and 26.9% (21/78) among Hispanic donors (*P* = .000006; Table 2). Among the donor age groups, donors <35 years had the highest declined authorization at 42.9% (51/119) and was significantly lower for donors between 35 and 49 years and ≥50 years [18.1% (21/116) and 16.3% (33/202), respectively; *P* < .0001]. The percentage of donors for whom NOK declined research authorization did not

Table 3. Percentage of Donor Families Declining Research Authorization by Donor Age, Donor Gender, and Donor Origin

Variable	Donor Family Research Authorization, % (n)		P ^a
	Declined	Approved	
Donor age (years)			<.000001
<35	42.9 (51/119)	57.1 (68/119)	
35-49	18.1 (21/116)	81.9 (95/116)	
≥ 50	16.3% (33/202)	83.7% (169/202)	
Donor gender			.35
Female	21.6 (37/171)	78.4 (134/171)	
Male	25.6 (68/266)	74.4 (198/266)	
Donor origin			.006
Local	35.8 (29/81)	64.2 (52/81)	
Imported	21.3 (76/356)	78.7 (280/356)	

^aPearson (uncorrected) chi-squared test with 2 degrees, 1 degree, and 1 degree of freedom for the tests of association with donor age, donor gender, and donor location, respectively.

significantly differ based on donor gender [21.6% (37/171) for females and 25.6% (68/266) for males; $P = .35$; Table 3]. Stepwise logistic regression found that there were 2 independent predictors of a higher likelihood of NOK research decline: donor age <35 years (multivariable $P < .0001$) and Black donor race ($P = .00002$). After controlling for these 2 factors, none of the other variables considered demonstrated additional predictive value.

Declined research authorization percentage was higher in donors from our “local” OPO at 35.8% (29/81) compared with donors from “imported” OPOs at 21.3% (76/356; $P = .006$; Table 3). However, there was a significant association of donor OPO origin with donor age. Donor age was significantly more likely to be ≥ 35 years for imported donors compared to local donors [76.7% (273/356) vs. 55.6% (45/81); $P = .0001$]. Thus, once the effect of donor age <35 vs. ≥ 35 years was controlled, donor OPO origin was no longer associated with the likelihood of the donor family declining research. We also considered the differences in research authorization among all the imported OPOs. After adjusting for the significant predictor variables (donor age and donor race) in the logistic regression model, there were no significant differences in research authorization between our local OPO and individual imported OPOs from across the USA (Supplementary Figure 1 and Supplementary Table 2). Cross-tabulation by donor age and race shows that research authorization decline percentage was lowest for White, Hispanic, and Asian races combined with the donor age 35 years and older, at 13.4% (34/254); research authorization decline was highest for Black donors age younger than 35 years, at 61.1% (22/36) (Supplementary Table 1).

DISCUSSION

Donor-oriented research plays a major role in increasing the quality and quantity of the deceased donor pool. The need for donor research authorization by itself makes sense to maintain the ethical directive of the public’s trust in the donation system and maintain transparency. In our study of organ donation offers from multiple OPOs, local and imported across the USA during a 12-month study period at 1 center, we observed a research authorization percentage of 76.0% across all donors and identified important disparities in consent for research authorization based on donor race/ethnicity. In particular, we found a statistically significant difference in research authorization decline by donor race/ethnicity. For Black donors, decline was 42.0%, nearly 3-fold higher compared to White donors and 1.6-fold higher compared to Hispanic donors. In multivariable analysis, donor age <35 years and Black donor race were the 2 significant predictors of research authorization decline. Specifically, research authorization decline percentage was lowest for White, Hispanic, and Asian donors aged ≥ 35 years at 13.4% (34/254) and highest for Black donors aged <35 years at 61.1% (22/36).

Recently, Lentine et al¹⁶ identified a difference in research authorization among Black donors based on data for 1 U.S.

Mid-Western OPO, with a higher decline rate of 16% compared to 8.9% in White donors. In that study, the decline rate was lower than that observed in our Black donor group, suggesting differences in OPO practices, as their study involved a single-center OPO, within their own DSA, whereas our study involves multiple OPOs across the country. Currently, there is a lack of uniformity in processes regarding NOK research consent requests, as well as training and guidance for research priorities in OPOs across the United States. With current emphasis on metrics for providing sufficient donor organs, there is increasing emphasis on the clinical yield of organs, and obtaining additional consent for research may be perceived as a deterrent to donor family authorization.

Our results related to research authorization parallel organ donation consent reports by Goldberg et al¹⁵ where Black race was associated with a lower organ donation consent rate of 54.9% compared to 77% among White and 67.5% in Hispanic decedents. Goldberg et al¹⁵ estimated that an additional 4719 transplantable organs could be added to the donor pool if Black decedents had consent rates similar to White decedents. Even though Blacks represent more than 40% of waitlisted candidates for kidney transplantation, organ donation rates are significantly lower in this group.¹⁸ Black participants have been a focus of many interventional trials to increase the outcomes of transplantation. Many of these studies need the research authorization from NOK. National Institutes of Health (NIH)-funded studies like the APOLLO Network and HOPE in Action rely on research authorization from NOK at the time of donation.^{7,8}

We found that donors aged ≥ 50 years had the lowest research authorization decline at 16.3% compared to 42.8% for donors aged <35 years. This pattern contrasts with the results of Lentine et al, where the research authorization decline rate was highest among donors older than 65 years at 16.7% compared to 11.8% in donors aged <40 years.¹⁶ These differences may relate to differences in study design. Our study did not include FPA among our donors, whereas Lentine et al were able to show a reduction in the decline rate by 55% when the donor provided FPA,¹⁶ which may explain the differences in declined authorization rate by age and other traits. Also, the demographic characteristics of our study populations differed.

Our analysis did not show a significant variation in research authorization between local and external OPOs once the association of younger donor age with locally procured donors was controlled. Overall rates of research authorization showed minor differences across OPOs across the country without any statistical significance. Goldberg et al¹⁵ were able to show differences in donation consent rates among different geographical areas of the USA. Regions with a predominant White race and younger age were shown to have higher donation consent rates.¹⁵ The differences in research authorization consent rates in our study could also be impacted from differences in practices by OPOs and hospital personnel and regional beliefs on

the value of organ transplant and medical research. Recently, a nationwide U.S. NIH-supported study that requires donor family NOK authorization developed an educational resource related to best practices in NOK research authorization after consent for organ donation, including guidance by OPO staff, transplant professionals, researchers, and, critically, donor family members.¹⁹

Ethical and logistical challenges involved when discussing the research authorization to donor families in a timely manner is further complicated by the ethnic dissimilarity between the requestor and the donor family. A study on differences between White and Black donor families at the time of consent for organ donation showed that Black NOK had less chance to meet an OPO donor coordinator compared to White (50.8% vs. 66.1%) and were less likely to participate in the donation request process when approached by non-Black requestors.²⁰ One 4-year retrospective study showed that using “like-to-like” ethnic requestors increased the organ donation rate by 115% among Black donor families.²¹ There are no studies looking at the same criteria for research authorization. Siminoff et al also showed that Black NOK had less explicit knowledge on the patient’s wishes compared to Whites, which gives them a major responsibility on organ donation and/or research authorization. More interventions to educate the requestors from different OPOs as well as the communities should be protocolized by appropriate authorities. Also, standardizing the donation consent purpose in the donor registry as to whether the donation is intended for transplantation and/or research will improve the trust among the donors and will help maintain a transparency in the request. In addition, UNOS DonorNet is currently not programmed to include donor authorization for research information in the inputted data; instead, it remains as a form to be uploaded by OPO personnel. This exclusion of authorization status in DonorNet makes it difficult to access the information to conduct approved studies and contributes to inconsistencies in the authorization forms among different OPOs.

The study has some limitations. First, it was a retrospective single-center study. Even though we received offers from across the USA, the single greatest number was our local OPO, and the donor demographics may not represent the entire organ donor population. However, the proportion of the Black donor group in our study was 22.9%, which was very similar to the Organ Procurement and Transplantation Network (OPTN) database on racial distribution of organ donors. Second, we did not have full information of donors with FPA and hence were not able to conclude on the declined rate for research by their NOK. This places the emphasis on UNOS DonorNet’s inclusion of the donor research authorization form and the need for uniformity among all OPOs. Third, since we involved multiple OPOs, their approaches to research authorization varies, and we do not have complete information on the protocol for obtaining consent by different OPO donor coordinators and

their requirements for specific study-based research consent. The involvement of study-specific consent may or may not have influenced the total consent rates.

CONCLUSION

In conclusion, based on all imported and local organ offers during a 12-month period from multiple OPOs at 1 large U.S. center, we found that deceased donor research authorization varied significantly with donor race and age, with Black race and donor age <35 years associated with the highest percent of research authorization decline. The understanding and facilitation of new approaches in education and communication with deceased donor families will ultimately provide a gateway to many innovative research projects that are designed to increase the quantity and quality of organ donation in transplantation.

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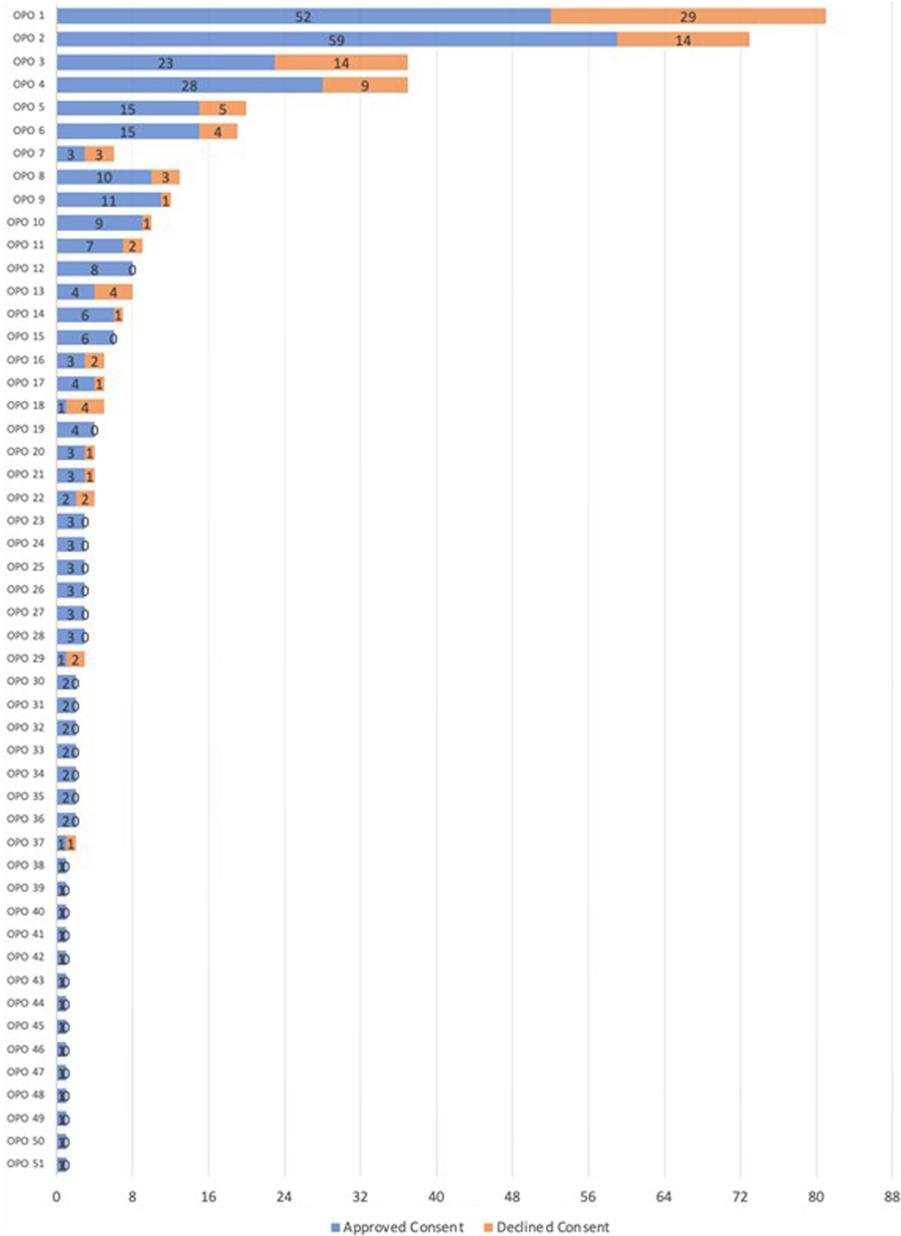
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Supplementary Figure 1. Next-of-Kin Declined vs Approved Consent for Research by individual Organ Procurement Organizations (OPOs). OPO #1 is considered our “local” OPO, within our Donor Service Area. OPOs #2-51 are considered outside our Donor Service Area (“imported”)

Supplementary Table 1. Cross-tabulations of Donor Age (< vs. ≥ 35 years) and Donor Race/Ethnicity (White, Hispanic, or Asian vs. Black) with the Likelihood of the Donor Family (NOK) declining Research Authorization

Donor Race/Ethnicity ¹	Donor Age ²	NOK declined research authorization
White, Hispanic or Asian	< 35	34.9% (29/83)
White, Hispanic or Asian	≥ 35	13.4% (34/254)
Black	< 35	61.1% (22/36)
Black	≥ 35	31.2% (20/64)

¹P ≤ .00007 in multivariate analysis.
²P < .000001 in multivariate analysis.

Supplementary Table 2. Next-of-Kin Declined vs Approved Consent for Research by individual Organ Procurement Organizations (OPOs)			
OPO #	Approved Consent	Declined Consent	Total
OPO 1	52	29	81
OPO 2	59	14	73
OPO 3	23	14	37
OPO 4	28	9	37
OPO 5	15	5	20
OPO 6	15	4	19
OPO 7	3	3	6
OPO 8	10	3	13
OPO 9	11	1	12
OPO 10	9	1	10
OPO 11	7	2	9
OPO 12	8	0	8
OPO 13	4	4	8
OPO 14	6	1	7
OPO 15	6	0	6
OPO 16	3	2	5
OPO 17	4	1	5
OPO 18	1	4	5
OPO 19	4	0	4
OPO 20	3	1	4
OPO 21	3	1	4
OPO 22	2	2	4
OPO 23	3	0	3
OPO 24	3	0	3
OPO 25	3	0	3
OPO 26	3	0	3
OPO 27	3	0	3
OPO 28	3	0	3
OPO 29	1	2	3
OPO 30	2	0	2
OPO 31	2	0	2
OPO 32	2	0	2
OPO 33	2	0	2
OPO 34	2	0	2
OPO 35	2	0	2
OPO 36	2	0	2
OPO 37	1	1	2
OPO 38	1	0	1

Supplementary Table 2. Next-of-Kin Declined vs Approved Consent for Research by individual Organ Procurement Organizations (OPOs) (Continued)			
OPO #	Approved Consent	Declined Consent	Total
OPO 39	1	0	1
OPO 40	1	0	1
OPO 41	1	0	1
OPO 42	1	0	1
OPO 43	1	0	1
OPO 44	1	0	1
OPO 45	1	0	1
OPO 46	1	0	1
OPO 47	1	0	1
OPO 48	1	0	1
OPO 49	1	0	1
OPO 50	1	0	1
OPO 51	1	0	1

OPO #1 is considered our "local" OPO, within our Donor Service Area.
OPOs #2-51 are considered outside our Donor Service Area ("imported").

(Continued)