PERFORMANCE SITE LOCATIONS

Project/Performance Site Locations		
Organization	Address	Primary Location
Bellevue Hospital Center	**462 First Avenue New York NY 10016-9196**	**Yes**

Abstract:

The recent IOM report *Organ Donation: Opportunities for Action* emphasized the substantial potential to expand organ donation following the cardiac determination of death. While promising results have occurred in controlled hospital settings, the prehospital setting has thus far yielded sparse donation opportunities. According to the IOM report, an additional 22,000 lives could be saved each year in the U.S. if patients underwent organ donation from uncontrolled donors after cardiac death (UDCD). This proposal describes the development of such a protocol with a consortium consisting of (1) Bellevue Hospital Center, a member of the New York City Health and Hospitals Corporation in affiliation with New York University School of Medicine (2) the NYC Emergency Medical Services (EMS), a part of the NYC Fire Department (FDNY), and (3) the New York Organ Donor Network (NYODN). This consortium will develop a model system for donation after uncontrolled cardiac death (UDCD), specifically for a multicultural population residing in an urban environment. The model system will be developed in consultation with all community stakeholders involved in organ donation including hospital, prehospital, and organ donor personnel as well as NYC and NY State government officials and community representatives who may be asked to participate. Once developed and approved by the stakeholders, the model system will be implemented and its impact tested within a defined geographic area served by Bellevue Hospital, a Level 1 Trauma Center and a principal receiving hospital for the NYC EMS system.

This collaboration will permit the development of protocols establishing a process whereby deceased patients ($\leq$ 60 years old) may legally undergo postmortem circulatory cannulation and corporal cooling following cardiac determination of death, preserving their opportunity to become organ donors as NYODN personnel determine whether the individuals are registered organ donors and/or if their families would agree to allow the donation to proceed. During the three-year project, interim qualitative and quantitative analysis of the community acceptance of the effort will be assessed with focus groups and a public education campaign developed and implemented. The program's impact on donations will be assessed with data collected by the organ donor counselors and the EMS providers. The ethical issues that arise in the public and professional communities will be addressed in a white paper. The goal of this program evaluation is to obtain consent from 25% of the eligible UDCD patients within the area surrounding Bellevue Hospital, leading to increases in donated organs, successful transplants, as well as supplying evidence that the protocol may be extended to the entire NYC EMS system.

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Project Title: Opportunities for Organ Donation: Expanding the Right to Donate Organs Following Uncontrolled Circulatory Determination of Death
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A. Introduction and Purpose

Many individuals have had their lives extended as recipients of transplanted kidneys, hearts, pancreas, liver, and other solid organs in the United States. Although there continue to be increased numbers of transplant recipients there are ever increasing numbers of transplant candidates, thus widening the gap between the supply of transplantable organs and the number of individuals on waiting lists. Currently almost all transplanted organs are retrieved following brain death and living donation.

The recent IOM report *Organ Donation: Opportunities for Action* (Childress et al., 2006) emphasized the substantial potential to expand organ donation opportunities following the cardiac determination of death. This process is now called organ donation from controlled donors after cardiac death (CDCD), and a policy facilitating this process in the hospital is required by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). In the hospital setting this process is a multi-layered one requiring first the decision to permit death and then the decision to proceed with donation. Whereas obtaining consent for organ donation following neurologic determination of death (i.e., "brain death") has clearly defined protocols and policies, protocols for obtaining consent for donation following cardiac determinations of death have begun to gain acceptance in most areas of the United States. Nonetheless, donation from CDCD in the hospital will gain access to relatively few organs as most cardiac deaths occur outside the hospital setting hereby referred to as uncontrolled donors after cardiac death (UDCD). Recent studies in Spain, (Alvarez et al., 1997, 2000; Gomez et al., 1993; Sanchez-Fructuoso et al., 2006) elsewhere in Europe and the U. S. (Light et al., 1997) have shown that well-integrated Emergency Medical Services (EMS), emergency departments, and transplantation services can effectively employ structured donation from UDCD to dramatically increase organ donation. These investigations demonstrated that model centers-of-excellence could be developed to identify and address institutional, professional and community barriers to donation from UDCD.

This proposal is designed to enhance public and professional education, disseminate best practices, and monitor and evaluate donation efforts from UDCD in a complex, multicultural city while adding preparation for organ donation to the end of standard cardiac resuscitation

protocols. Previous experience in the US (Light et al., 1997) has demonstrated that top-down professional and political support as well as broad-based grassroots community support are necessary for acceptance and successful implementation of a donation program from UDCD. Engagement of all community stakeholders will be conducted to develop a public education campaign that will be embraced by the communities served. A feasibility study for implementing the protocol in the entire NYC EMS system will be conducted in one of its Bellevue Hospital's extended catchment areas.

The primary aims of this proposal are as follows:

1. Conduct outreach and engage dialogue with all stakeholders to derive the donation protocol for UDCD including
    - HHC Ethics Committees and Community Boards;
    - Prior recipients of donated organs and their families;
    - Leadership of the NYC Department of Health, the NYC Health and Hospitals Corporation, the NYC Regional Emergency Medical Advisory Committee and the Manhattan Borough Medical Examiner;
    - Ethics scholars in New York and the surrounding area;
    - Leadership organizations from all socio-ethnic communities served by Bellevue;
    - Staff of transplantation teams, EMS, and emergency departments of NYC hospitals who are likely to be involved in the procurement and transplantation process and
    - Religious health ministries, hospital chaplaincies, and patient advocacy;
2. Develop a consensus on the need for and approach to a donation program from UDCD as well as a foundation for a public education campaign
3. Develop and implement an effective public education campaign to obtain acceptance for the donation program from UDCD
4. Evaluate the impact from UDCD program and assess the feasibility to extend the program into the entire NYC prehospital and hospital network.

The goal of this proposal is to explore a novel approach that utilizes the current organ donation infrastructure of a metropolitan area to improve the number of donated organs and thus transplants. The potential increase in organs procured may save many of the lives of the increasing number of patients awaiting organ transplantation.

B. Needs Assessment

Current state of organ donation: The shortage of donors

Over 90,000 patients await organ transplantation annually with only approximately 7,600 deceased and 6,900 living donors meeting the demand (UNOS 2005). The major contributing factor to this shortage is that no more than 50% of eligible decedent families agree to organ donation (Gortmaker et al., 1998; Siminoff et al., 2001; UNOS 2004). Despite having on average of three organs per deceased donor available for transplantation and the contributions of 6,900 living donors, only 28,108 patients received transplants in the United States in 2005, resulting in the deaths of 7,170 individuals while awaiting organs (UNOS 2005).

Traditional approaches to increasing the number of available organs include legislation, donor recruitment campaigns, and registration initiatives, all geared to increasing the number of organs from those dying following determination of brain death. Legislators, organ procurement organizations, and private foundations have focused on community interventions and changing procurement policy to improve organ donation rates (Boulware et al., 2002). To reduce public suspicion concerning the medical establishment's potential to procure organs from patients prior to death, state legislatures enacted laws delineating strict criteria for brain death and introduced the "dead donor rule" stipulating that vital organs should only be taken from dead patients and living patients should not be killed for or by organ procurement (Arnold et al., 1993; Youngner et al., 1993). State legislatures enacted the Uniform Anatomical Gift Act authorizing persons 18 years of age or older to make a gift of any part of their bodies upon death and that, the gift could not be rescinded by another party without the donor's consent (Organ Donor 2006). States further consider carrying an organ donor card, signing one's driver's license, enrollment into a state registry, or signing a family attestation form as legal proof of an individual's organ donation wishes.

Despite the law, a survey of organ procurement organizations indicated that a majority would refuse an anatomical gift if the donor's family objects (Wendler et al., 2001). This practice may be based on concern about adverse publicity, a tendency to respect wishes of living persons in lieu of the decedent, and or fear of legal liability if the organ procurement organization acts against family wishes (Organ Donor 2006). Organ procurement organizations may refuse an anatomical gift, for the law imposes no penalty for failing to comply with donor wishes (Organ Donor 2006). States now are enacting legislation emphasizing registration in an organ donor registry as evidence of decedent wishes, and are moving toward a policy of informing family members of the impending donation, rather than asking for their permission (Organ Donor 2006). It is yet to be determined how this legislation will impact organ donation, but the emphasis of documentation will be to encourage registration in state organ donor registries in lieu of traditional methods including drivers' licenses and organ donor cards, which often are not available at the time of the donation request (Organ Donor 2006).

Since organ procurement organizations are reluctant to act contrary to family wishes, their initiatives are directed towards improving family education and enhancing discussion about organ donation. These initiatives include the Donate Life advertising campaign, work place educational programs, Internet education, and on-line enrollment into organ donation registries (Organ 2007). Public and private foundation support has also led to development of educational programs for youth in classroom settings (James Redford 2006), documentaries (James Redford 2006; Wisconsin 2006) , news broadcasts (PBS 2007), Internet modules (TransWeb 2007; Donate 2007), and kiosks (Self Service 2007) to increase public awareness about organ donation and encourage enrollment into organ donor registries. Even with all these initiatives, the organ donation rate remains at 50% (UNOS 2004, 2005).

Donations after Cardiac Determination of Death

By expanding organ donation opportunities to include uncontrolled cardiac determination of death, steps toward the Healthy People 2010 goal of reducing complications, disability, death and economic costs of chronic kidney disease can be achieved. Conversely, without considering donation from UDCD it is unlikely that the pool of available organs would significantly impact

upon the goal as the demand for organs would continue to outpace the supply. Much can be learned from the Madrid, Spain experience. Through the evaluation and outcomes of this proposed pilot, with the goal to specifically addressing attitudes about organ donation, approaches can be designed to address two vital objectives: (1) Increasing the proportion of dialysis patients on the waiting list for transplantation; (2) increasing the proportion of patients with treated chronic kidney failure who receive a transplant within 3 years of registering on the waiting list.

For almost 20 years the Madrid, Spain Emergency Health System has had a formal hospital agreement establishing a standard protocol for obtaining organs from patients with sudden out-of-hospital death. (Alvarez et al., 1997, 2000; Gomezet al., 1993; Sanchez-Fructuoso et al., 2006). Patients in Madrid with irreversible cardiac death are no longer brought to the morgue but to the hospital for organ donation. These patients all have failed cardiopulmonary resuscitation and donation is only considered following the performance of all measures and times specified for established cardiopulmonary resuscitation (CPR) and Advanced Cardiac Life Support (ACLS) procedures or the injuries resulting in cardiac arrest are felt to be incompatible with life. The following conditions must also be established in the Madrid criteria: a known cause of death, the absence of violence, a known time of cardiac arrest, the absence of injury to the thorax or abdomen with resultant hemorrhage (avoiding additional hemorrhage with cardiopulmonary bypass for organ procurement), the performance of external CPR and mechanical ventilation within 15 minutes of cardiac arrest, the absence of evidence of intravenous drug use suggesting associated viral infections (HIV, Hepatitis, B/C), and a donor age < 60 years.

When the individual is a potential donor, the resuscitation team continues cardiac massage, mechanical ventilation, and intravenous fluid perfusion to maximize hemodynamic performance during transport. Upon arrival at the emergency department the transplant coordination team evaluates the prerequisites for donation. At this time, the femoral artery and vein are cannulated, cardiopulmonary bypass, external oxygenation and hypothermia are established. The patient is brought to the operating room when necessary consent is obtained. The Madrid investigators have employed a maximum warm ischemia time (from start of cardiac arrest until bypass) of 120 minutes and a maximum pump cold perfusion time of 240 minutes. During the perfusion period the transplant coordination team fulfills the legal requirements for donation.

In the last several years consensus recommendations in the US (Bernat et al., 2006) and in Canada (Shemie et al., 2006) have suggested the expanded practice of donation from DCD in the continuum of quality end-of-life care. These consensus documents affirmed the ethical propriety while maintaining the "dead donor" rule and suggested principles essential to establishing an integrated collaborative system involving (1) all hospital stakeholders including emergency department, ICU, operating room, risk management, pastoral care and bioethics; (2) communication, information and education of the above staff; and (3) communication, information and education of the public.

Despite the success of transplantation with organs procured from donors deceased from cardiac determinations of death in controlled and uncontrolled settings, only recently has the U.S. realized gains from such donation opportunities, with the overwhelming majority of them

secured in controlled hospital settings. In 2005, there were 473 donations from those deceased from cardiac determinations of death, with only 15 of them occurring in uncontrolled settings (Punch et al., 2007). Studies have shown that while successful kidney transplants from DCD rivals the success rate from those deceased from neurological causes, DCD livers have significantly lower graft survival rates. The three year graft survival rate was 75% for livers procured from brain death donors versus 61% from DCD donors (Merion et al., 2006; Mateo et al., 2006; Doshi et al., 2007; Lee et al., 2006) determined from a subset analysis that while the liver graft survival rates were superior with livers procured from brain dead donors < 65 years old, the livers procured from those dying of cardiac causes were similar to brain death donor livers from patients 60 years of age and older or split livers, suggesting that for these patients, DCD livers are viable options compared to these alternatives. Furthermore, using modified Madrid criteria in UDCD patients may achieve similar if not improved results, especially with a concerted effort to cool these patients at the time of death determination.

Gaps in the literature

While donation after cardiac determination of death protocols have been successful in European nations, and to a lesser degree in some U.S. cities, no U.S. EMS system to date has attempted to establish such an approach for its service area. Furthermore, pre-existing UCDD donation protocols have been based on the Madrid criteria, criteria that may unnecessarily exclude viable organs, especially kidneys because it excludes victims of trauma.

Research hypothesis for implementing an uncontrolled DCD protocol in NYC

Our hypothesis is that the NYC community stakeholders involved in organ donation will form a consensus statement regarding the establishment of a mutually agreed upon donation protocol from UDCD. We further hypothesize that such a protocol will capture 25% of the eligible UDCD, leading to increases in organ donations and successful transplants. For these reasons, we propose a pilot study to implement a UDCD donation protocol in an extensive area surrounding Bellevue Hospital with the overall goal of establishing a citywide donation protocol from UDCD for the entire NYC EMS system.

Preliminary Studies/Progress Report

American Heart Association Projections: Feasibility for this study is supported by data from the American Heart Association (AHA). The American Heart Association (AHA) has estimated that about 335,000 deaths occur annually due to sudden cardiac arrest (AHA 2007). The AHA estimates that approximately 95% of these patients die prior to reaching the hospital. In a study of cardiac arrest survival in the City of New York, a comparable percentage of patients did not survive to reach the hospital (Lombardi et al., 1994). This New York City prehospital cardiac arrest survival evaluation (PHASE) enrolled 2,329 consecutive patients with out-of-hospital cardiac arrests in New York City. Although the PHASE study occurred during the early 1990s the age of the patients, the percent with bystander CPR, those for whom EMS responded within fifteen minutes of collapse and the median time of CPR performance are known. These parameters, established from the largest consecutive series of out of hospital cardiac arrests, will permit the investigators to determine the number of potential candidates for organ donation as UDCD who would meet varied UDCD criteria based on a consensus perspective of best practices of transplantation surgeons for specific organs at the time of this current study. Applying the very conservative modified Madrid criteria (Alvarez et al., 1997; Sanchez-Fructuoso et al., 2006)

for the PHASE data approximately 7.6% of out-of-hospital cardiac arrest patients in NYC would have been eligible to meet donor criteria. These 178 of 2,329 patients in the NYC study when extrapolated to cardiac arrest data in the United States each year would yield 22,000 decedents who meet the modified Madrid criteria for donation as UDCD. These numbers far exceed the current number of eligible donors through neurological death. It is this important hypothetical analysis of the potential number of donors from a largely underutilized source of patients in New York City and the USA that makes this study so consequential to the public's health. It is these patients whom we believe should be evaluated for their desires if they are members of a donor registry, and it is their families whom we believe should be offered the opportunity to donate their loved ones' organs.

NYC EMS Projections: Examination of 2006 New York City Fire Department (FDNY) data for patients ≤ 60 years who sustained cardiac arrest and underwent CPR in the borough of Manhattan reveals that 36 patients were pronounced dead on scene, and 103 patients were transported to a hospital. Allowing for approximately 3% survival results in 100 patients who probably were pronounced dead in the hospital or a total of 136 potential donors cared for by FDNY-EMS. Since FDNY cares for 60% of the NYC 911 system call volume (voluntary ambulances respond to the remainder of these calls), adjusting for the relative share of FDNY in the NYC EMS 911 system , results in an estimate of 227 patients in 2006 in Manhattan who could have potentially met the criteria for donor eligibility (approximately 4 patients / week). Expanding the study's catchment area to adjacent boroughs (e.g., Brooklyn, Queens, and the Bronx) would significantly increase these numbers of potential donors. These data represent substantial support for the feasibility of this study.

Establishment of the Consortium: For the past seven months, the proposed consortium has held successful monthly work group meetings to discuss implementation of a donation protocol for UDCD for NYC EMS. The group, consisting of 1) Lewis Goldfrank, MD, Chairman of the NYU School of Medicine Department of Emergency Medicine and Director of the Bellevue Hospital Emergency Department; 2) Eric Grossman, MD, Medical director of the New York Organ Donor Network; 3) Bradley Kaufman, MD, MPH, Deputy Medical Director of FDNY-EMS; 4) Nancy Dubler, LLB, an organ donation bioethicist; 5) Stephen Wall, MD, MS, an AHRQ funded methodologist and statistician specializing in organ donation research; and 6) Ramanathan Raju, MD, Executive Vice President for medical and professional affairs of the NYC Health and Hospitals Corporation, identified potential political, ethical, social, and procedural barriers to implementing such a protocol in NYC and developed a preliminary donation protocol for UDCD for this proposal (see interventions section). This consortium has presented this plan to the NYC Health and Hospitals Corporation leadership, who have conveyed their support for this initiative as a matter of consequence to public health.

C. Methodology

Summary

Mixed methods will be used to conduct the donation program evaluation for UDCD. Using the protocol developed with our preliminary consortium meetings as a guide, experienced qualitative researchers will conduct focus groups with all the stakeholders involved in organ donation to determine the barriers to implementation of the protocol as well as formulate consensus opinions

regarding protocol changes to ensure ultimate successful implementation. Marketing research specialists will, in turn, gage public opinions surrounding donations from those undergoing UDCD, and a preparatory public relations campaign will be conducted to secure favorable public opinions about the proposed changes in donation protocols. After these preparatory procedures are conducted, the program will be implemented concurrent with a formal program evaluation of its impact on donations and successful transplants. The following sections provide detailed information about each phase of the proposed research.

Interventions

Preparatory Interventions:

(1) Administrative support.
Discussion will be held to obtain the full support of the City and State Commissioners of Health, the NYC Medical Examiner, the NYC Fire Commissioner, the City and State Attorneys General, and possibly the Mayor. These efforts have begun in general at various levels and will be expanded as precise details of this study are developed.

(2) Stakeholder focus groups
Focus groups will be conducted with all stakeholders involved in organ donation, in order to understand the barriers to implementing the protocol for UDCD and to refine it so that it adheres to the consensus opinions surrounding its successful implementation. The effort will be led by an experienced qualitative research team from the NYU Department of Educational Informatics, a group having experienced focus group facilitators, audio-visual personnel, and qualitative data coders. Focus groups will be conducted among the following stakeholders including: 1) NYC HHC administrators, 2) FDNY-EMS personnel, 3) NYODN personnel, 4) Bellevue Hospital Emergency Department Providers, 5) Transplant surgeons, 6) bioethicists, and 7) community stakeholders from the multiethnic community served by Bellevue hospital stratified by socio-ethnic group (e.g., Latinos, Non-Latino Whites, African Americans, and Asian Americans). Focus groups will have eight participants per group and will be recorded with digital audio equipment. The results from the focus group analysis will be a thorough understanding of the barriers to implementing a donation protocol for UDCD as well as formulating a mutually agreed upon protocol prior to initiating the program evaluation. This protocol will be brought back to a focus group having representatives from each stakeholder group for final revisions and confirmation of its acceptance and feasibility.

(3) Getting grassroots community support.
Similar to the model successfully employed in Washington, DC (Light et al., 1997) constituent community groups, such as the Community Advisory Boards and Community Planning Boards served by Bellevue Hospital, will be approached for their input and support of the Rapid Organ Recovery Program. These groups will be informed about the great need for organs in New York City, the impact of the limitation of organs on families and communities, and the access all New Yorkers have to kidney transplant through the CMS ESRD program. The Rapid Organ Recovery Program will be presented as a program that preserves the individual's right to donate organs and save lives. This effort will be presented as an innovation in the context of the other NYFD efforts aimed at improving the care of people with injury or cardiac arrests. The community organizations will have the opportunity

to provide input into the implementation of the program as well as the public education that will precede the launch of the program.

The New York Organ Donor Network already works with community groups to conduct outreach and education programs. NYODN has had extensive experience in outreach to the African American, Latino and Asian American communities, precisely those communities most served by Bellevue. These continuing efforts are prompting potential donors to move from a state of contemplation to a state of action, as measured by increases observed in joining the donor registry and the significantly increased percentage of families in New York City that initiate the discussion of organ donation when loved ones are in a position to become potential organ donors.

(4) Public education initiative.

Information gathered from stakeholders and the target community at the grass roots level will be utilized to design a strategic public education campaign. A nationally recognized public relations firm, in collaboration with the Donor Network, will design the tactics and strategy of the campaign. The campaign will include a pre and post campaign evaluation to test the effectiveness of these tactics as well as to assess outcome post implementation. The testing will comprise focus groups to test message points and delivery tactics such as radio, print and electronic advertisements and public service announcements designed to target specific constituent groups. Methodology will utilize current state-of-the art social marketing techniques.

There is growing evidence that public education campaigns have been effective at raising knowledge about organ transplantation and creating more favorable attitudes toward organ donation. As an example, the National Minority Organ/Tissue Transplant Education Program (MOTTEP) has been conducting outreach efforts in minority communities in several cities nationwide since 1978. (Callender et al., 2002) Like the proposed study, the MOTTEP program combines in-person grassroots campaigning with multimedia advertisements. MOTTEP researchers cite large increases in the consent rate over time and in the number of black donors in those cities in which MOTTEP was conducted as evidence of the program's effectiveness (Callender et al., 2002, 2004).

National studies have documented generally favorable attitudes toward organ donation. A 1993 Gallup poll found that 95% of people were aware of transplantation and 73% would be willing to donate at their death (Gallup, 1993). The 2005 National Public Opinion Survey on Organ Donation (Gallup, 2005) found that Americans continue to support strongly the concept of donating organs or tissues for transplants. The proportion of survey respondents who said they would be likely or very likely to have their organs donated rose from 73% in 1993 to 78% in 2005. About four in five Whites (82%) indicated they were likely or very likely to donate their organs; about three-fourth of Latinos (75%), three-fourths (75%) of Asians and three- fifth (64%) Blacks indicated they were likely to donate their organs.

Despite national surveys that indicate a positive view of organ donation, in reality, the consent rate for donation nationwide is less than 60 percent. In the greater New York metropolitan area, there is a 56 percent consent rate which is significantly higher than in the recent past. Nationally, there has been a 4-point increase and in the New York metropolitan area, the rate has increased by a dramatic 10 points over the past few years. The focus of this

campaign will be to generate support for donations from UDCD and organ donation in general, as perceptions of this may yield distrust among the populations served by FDNY-EMS and Bellevue Hospital.

Primary Interventions:

The primary interventions are (1) the dispatch of the Rapid Organ Recovery Ambulance personnel and conveyance of the potential organ donor to Bellevue Hospital; (2) the cooling of the kidneys, and possibly liver, through the intravascular and intraperitoneal routes; (3) the identification and locating of the family and the approach to the family for consent to donate; and (4) the emergent recovery of the kidneys, and possibly liver, once consent is obtained. Subsidiary to these activities are the interventions that relate to the treatment and allocation of the organs following recovery – which will occur according to the existing standard operating procedures of NYODN. Specifically, the preservation of kidneys will occur by the initiation of pulsatile pumping using Organ Recovery Services LifePort technology. New York Organ Donor Network (NYODN) currently utilizes this approach on all locally recovered and imported kidneys, and currently pumps more kidneys in the US then any other Organ Procurement Organization (OPO). Allocation will occur on-site at Bellevue Hospital by NYODN recovery personnel according to UNOS rules, regulations and technology (DonorNet). The NYU transplant team will be responsible for recovery of the organs and assessing perfusion quality in a timely fashion. In addition to the primary interventions, there will be preparatory interventions that will occur mostly in the first year of the grant period.

(1) Description of the New York City EMS Prehospital Phase of UDCD

When a 911 call is received with a potential cardiac arrest, two ambulances (one Advanced Life Support (ALS) and one Basic Life Support (BLS)) and a fire engine (with Certified First Responders) are dispatched to the scene. The first arriving crew will inform the dispatcher if the patient is confirmed to be in cardiac arrest and if cardiopulmonary resuscitation (CPR) has been initiated (either by the emergency responders or by bystanders prior to emergency crew arrival). If CPR is performed, the prehospital UDCD procedures will be initiated.

CPR may not be initiated by the emergency responders for a patient in cardiac arrest under certain circumstances. For instance, a patient may have a valid 'Do Not Resuscitate' (DNR) order. If the deceased patient does not have signs of 'prolonged death' (e.g., dependent lividity, rigor mortis, pooling, etc.), then prehospital UDCD procedures will be followed as described below.

Prehospital UDCD procedures will entail the immediate dispatch of a specialized FDNY ambulance, designated the Rapid Organ Recovery Ambulance (RORA). The RORA crew will consist of a family services coordinator (FSC) and two Emergency Medical Technician's (EMTs). This ambulance will operate one 8 hour tour per day, 7 days per week. Review of the 2006 hourly distribution of cardiac arrest ambulance calls in NYC and in the borough of Manhattan demonstrates an almost equal hourly distribution throughout the day and night. Therefore, traffic concerns, operating room availability, and family consent considerations may dictate night operation of this protocol. As time to cannulation and initiation of preservation measures are critical to organ viability (i.e. minimization of warm ischemia period), an attempt

will be made to obtain approval for the use of lights-and-sirens to transport the potential donor to Bellevue (for most rapid transport from field to the hospital). The ambulance will carry an automated chest compression device, an external hypothermia device, and a transport ventilator.

If prehospital resuscitation is successful, and the patient achieves return of spontaneous circulation (ROSC), then he or she will be transported to the nearest hospital. At the discretion of the emergency responders and on-line medical control physician, (OLMC) a patient in cardiac arrest may be transported to the closest hospital with ongoing CPR. In either of these scenarios, the patient may subsequently be pronounced dead in the hospital emergency department (either returning cardiac arrest after prehospital ROSC, or never regaining ROSC). If this hospital emergency department happens to be Bellevue, then UDCD procedure may be continued at that point. If the hospital is not Bellevue, then the standard EMS protocol prevails at that point. During Phase I, interhospital transport of UDCD may be assessed, recognizing the challenges of addressing medical examiner issues of handling dead bodies that have been pronounced dead, perceptions of the family, and the administrative concerns of sending/receiving institution.

If resuscitation is terminated in the field when the patient is pronounced dead by the OLMC the RORA crew will perform the following prehospital UDCD procedures. First, they will determine if the deceased patient meets the UDCD inclusion and/or exclusion criteria. If the deceased is an appropriate candidate for potential transplantation, the RORA crew will resume chest compressions and ventilations after a hands-off period of two minutes (to allow for the possibility of a spontaneous return of cardiac activity), and transport the deceased patient to the Bellevue Emergency Department. The RORA Family Services Coordinator (FSC) will initiate family counseling and consent procedures as soon as the deceased is deemed to be an eligible donor. In the event of obvious signs of death, or if UDCD criteria are not met, the deceased patient will be transported to the medical examiner as is standard protocol. (See Attachment 6A)

(2) The identification and locating of the family and the approach to the family for consent to donate.

A trained FSC will be a member of the Rapid Organ Recovery Ambulance and will respond to each dispatch call with the EMS team on the ambulance. Upon arrival at the scene of the cardiac arrest, the FSC will ascertain whether the family of the patient is present. If the family is present, the FSC will initiate contact with the family and provide information about the procedures that are being utilized to treat their loved one, and will give them appropriate emotional support and other assistance, as needed (such as helping them contact other family members). This is truly a value-added aspect of the Rapid Organ Recovery Program, as the EMS team usually consists only of those who provide direct patient care. If the family is not present, the FSC will begin to gather information from the other people at the scene to identify the patient and begin to locate the family. Once again, this is another value-added aspect of the program as family members will be more likely to be notified sooner of the status of their loved one because of the efforts of the FSC. If the patient is resuscitated and is able to be transported to Bellevue the FSC can continue family support and introduction to the ED staff. If the patient's family is present and the patient cannot be resuscitated, the FSC can initiate discussions about the opportunity for donation. If the patient's family is not present, the FSC will continue to try to locate and then communicate with

the family, and then present the donation opportunity. It will also be the role of the FSC to initiate contact with the Medical Examiner to obtain clearance and arrange for formal declaration of death, as well as to collect and record donor data (see Variables, Outcome Measures and Evaluation, and Instruments sections below).

The New York Organ Donor Network (NYODN) utilizes the dual advocacy approach when obtaining consent for organ donation, and every FSC at NYODN is highly trained in this technique. Dual advocacy will serve as the foundation for the approach on this project with modifications being made as necessitated by the acute nature of a UDCD scenario. The modifications to the dual advocacy approach will be determined through research done by Dr. Steven Wall and the NYODN during the first year of the grant period (as part of Dr. Wall's AHRQ funded research). The concept of dual advocacy challenges the requestor to recognize and respect each family's right to make its own fully informed decision. In utilizing this approach, the requestor advocates for both the potential donor family and the waiting recipients by helping the donor family to understand the overwhelming need for life-saving organs and to recognize the rare opportunity the family has to save and improve the lives of potential recipients and their families.

(3) Description of the Bellevue Emergency Department Phase

The Emergency Department staff will be notified by the RORA crew that a patient who is a potential candidate for UDCD is enroute to the Bellevue ED. The RORA crew will give an estimated time of arrival. The deceased patient will be transported from the RORA to the Bellevue Hospital Emergency Ward resuscitation area. (see Attachment 6B – Flowchart)

The RORA notification will alert ED staff to prepare for patient arrival, which includes calling the transplant team, the Emergency Department attending physician and senior resident, the charge nurse in the Emergency Ward and the respiratory therapist to place the patient on a ventilator. The patient will arrive with continuous CPR (Autopulse CPR device) and mechanical ventilation performed by the EMS personnel. The ED attending will reconfirm that there is no evidence of violence, no evidence of cancer or HIV/AIDS (with a rapid HIV test) and no evidence of serious chest or abdominal trauma.

The appropriate materials will be available in the Emergency Ward for the transplantation team including cannulation devices and an autopulse CPR device. In the absence of donor status confirmation, the surgical team will begin cannulation and cooling, obtain requisite blood samples under prior community agreement of presumed consent to preserve the opportunity to donate pending next of kin approval.

Total warm ischemia time: from the moment of collapse until the establishment of organ preservation will be less than one hour. While preservation procedures are begun, efforts will continue regarding standard death notification. The medical examiner will be contacted according to standard protocols, donation will continue to be requested from family by a FSC from the Organ Donor Network, and in situ cold ischemia will not exceed four hours.

(4) The emergent recovery of organs

Organ procurement will ensue per standard procedures. The transplant surgeon on call will arrive to procure the organs according to pre-established guidelines, though modifications may be made based on whether the liver is viable (derived from parameters including patient down time and time to cooling and resuscitation). The NYU transplant team will develop a reproducible scale to assess donor organ perfusion and quality. Organs will be allocated according to standard OPO network guidelines.

Potential of these interventions to be replicated

All of the interventions that are described are readily transferable. The fact that the unique challenges of establishing a program for UDCD in a complex urban environment such as New York City have been comprehensively addressed in this proposal enhances the possibility that other urban locations will be able to use this program as a model. Suburban or more rural environments are likely to be less complex, and therefore may be able to implement elements of the program which are appropriate to their needs and still be successful. A truly rural location may have significant difficulties in responding to and transporting a potential donor and may need specialized techniques not addressed in this proposal.

Target Population

Bellevue Hospital Center serves a population that disproportionately includes ethnic and linguistic minority and immigrant groups who often have limited English proficiency and low health literacy. Annually, nearly 28,000 patients are discharged, and 85,000 emergency visits and over 500,000 ambulatory care visits are provided. More than half the patients who seek care at Bellevue Hospital Center prefer to communicate in languages other than English. While Spanish, Mandarin, Cantonese, Polish, Bengali and French are the predominant other-than-English languages, over 60 languages are routinely requested through Bellevue's interpreting program. In New York City more than 140 languages are spoken. Bellevue's catchment areas stretch across as many as 63 zip codes, covering large sections of 3 of the City's 5 boroughs. The study team is attuned to the specific needs of this multiethnic population, having extensive experience serving its medical needs, as well as having conducted successful research endeavors to improve the care delivered to its members. Performing organ donation research that is inclusive of multicultural populations supports the need to both educate and cultivate donations from communities that have historically been underrepresented as potential donors.

Settings

The setting for this research is the point at which prehopsital arrests occur in the area surrounding Bellevue Hospital, as well as the Bellevue Emergency Department and operating suites. These are the settings where uncontrolled donations occur, and traditionally where organs are procured. The focus groups will be held on a neutral site yet to be determined.

Variables

Data will originate from four crucial, but distinct components in the pre-hospital donation process. The four components are the initial evaluation and non-invasive cooling by the pre-hospital team, family identification and donation request by the family services coordinator, the invasive cooling and organ recovery by the in-hospital staff, and outcome in the recipient. Each

component will have its own data-gathering instruments applicable to its process. Linkages between these data will be accomplished by the utilization of a unique identification number that is generated each time the pre-hospital unit responds to a case.

Five outcome variables will be analyzed as independent variables to assess the program's overall effectiveness in increasing the organ supply. They are: overall donor potential, donor conversion rate, organs recovered per donor, organs transplanted per donor, and survival of the organ following transplantation. All other variables described below will be considered dependent variables.

Data acquisition will begin with the dispatch of the Rapid Organ Recovery Ambulance. Every dispatch will require the team to gather basic demographic and clinical information from the initial EMS responders. Datapoints will include age, sex, race, ethnicity, location of arrest, and time of arrival on-scene by both the EMS providers and the RORA team (consisting of 2 EMTs and a FSC).

If it is determined that the patient meets the criteria for pre-hospital donation at the time of declaration, the RORA team will begin capturing the relevant time intervals regarding warm ischemia time in the field. They will include:

- Time patient was last seen alive: This will describe the maximum length of time that the patient could have been in cardiac arrest prior to the initiation of CPR.
- Time CPR was initiated (either by bystander or rescuer)
- Time CPR was terminated
- Time of death
- Time when the non-invasive cooling process was initiated by the pre-hospital donation team
- Time of patient physically entering the Emergency Department at Bellevue

In addition to the time intervals, the RORA team will complete a checklist of interventions performed prior to arriving at the hospital.

Concurrent with the RORA team's evaluation of the patient, the FSC will also record data on next-of-kin. This will include name, address/contact information, and relationship to the patient. In addition to a narrative describing the actions undertaken, the FSC will record data on well-defined events at the scene, such as:

- If the next-of-kin witnessed the arrest
- If the next-of-kin was present at the scene when EMS arrived
- The length of time of interaction between the FSC and the next-of-kin at the scene
- When and where the donation request was made (i.e. at the scene versus the hospital)
- The length of time it took to locate the next-of-kin if they were not present at the scene
- Whether or not a prior discussion about donation took place between the next-of-kin and the patient (i.e. knowing the patient's wishes)
- The patient's status on the New York Donor Registry

Furthermore, variables that assess the circumstances of donation request adherence to best practices will be captured. Best practices established within the organ donation field with in-hospital patients include whether or not the donation request was made in a private place (and not at the bedside), if hospital personnel participated in the donation request, if the discussion mentioned the scarcity of the supply of organs, and whether the patient had discussed donation with the next-of-kin. Additional factors to be analyzed will be ascertained during the first year of the project (phase 1) with data on the consenting procedure in the setting of UDCD donations.

Upon arrival to the Emergency Department at Bellevue, the RORA and recovery personnel will use a modified version of the NYODN standard donor evaluation form. The standard donor evaluation form contains the patient's admission course, physical examination, laboratory values (including blood type), medical / social history questionnaire, and infectious disease testing results. Modifications will include the addition of these variables:

- Time of cannulation
- Type and amount of cooling fluid used
- Duration of warm ischemic time
- Duration and degree of cooling in transport determined by a rectal thermometer
- Duration of time between *in situ* cooling and recovery
- Surgical errors, if any, occurring during the recovery

The number and type of organs recovered and transplanted will be recorded for every organ donor. Any diagnostic procedures performed on the organ (i.e. biopsies) and their results will also be recorded. For the kidneys, pulsatile preservation data will be included in the recovery dataset. In the event of an organ discard, the reason for the discard will also be recorded.

Every dispatch by the pre-hospital team, regardless of its donation outcome, will be catalogued by data entry staff within a central database for future analysis.

Outcome Measures and Evaluation Plan

The principal goal of the program is to increase the organ supply by expanding the donor pool. One primary analysis and three secondary analyses will be performed in order to assess whether this goal has been attained.

The primary analysis will assess whether the donor conversion rate exceeds a predetermined goal of 25%. Three other analyses will examine other important transplant metrics. These metrics are: organs transplanted per donor, 6-month patient/graft survival rates, and the overall cost/benefit ratio.

The Primary Outcome Measure: Donor Conversion Rate

Donor Conversion Rate (DCR) is the number of actual donors divided by the number of eligible donors. The investigators feel that a 25 percent donation rate is the lower-bound of what is acceptable through pre-hospital donation and this would represent a highly clinically significant increase in kidneys available for transplant originating in the New York City metropolitan area.

Using data from the PHASE study, (Lombardi et al., 1994) achievement of this donation rate would lead to a 22 percent increase in the local kidney supply if the model is applied citywide. In order to establish significance in the conversion rate, a minimum sample of 30 would be required to provide a two-tailed alpha of 0.05 and a power of 0.90.

Given our donor conversion rate (DCR) of approximately 60 percent in the donation following brain Death (DBD) population, a 25 percent conversion rate in the intervention group may seem to be a modest goal. This lower estimate is due in large part to the acute setting in which the donation request is made wherein which family may not be identifiable or contactable. In addition, in contrast to the DBD population, FSCs making the donation request will be operating under significant time constraints (to minimize warm ischemia time and in-situ cold ischemia time), precluding the ability of the FSC to engage the next-of-kin to the degree that is possible in a conventional organ donation setting. It should be noted that the DCR selected is approximately at the level obtained when approaching families in the NYC area for consent to donate tissues.

(1) Organs Transplanted Per Donor

Patient demographics, time intervals between cooling process endpoints, donor medical and social history, laboratory values, and transportation time from the scene to the hospital will be included in an analysis of their effect on the number of organs recovered and transplanted. One area of focus will be on the determinants of recovering and transplanting the liver from this population using the available data.

(2) Six Month Patient and Graft Survival Rates

Six month transplant outcomes will also be analyzed using both available donor and recipient data. For kidneys, the independent variables will be patient survival, graft survival, post-transplant complications including ureteral leak and graft performance (as measured by glomerular filtration rate and creatinine). For livers, the independent variables will be patient survival, graft survival, pre and post transplantation liver biopsy and hepatic enzymes and post-transplant complications including late bileduct injuries. Methods of analysis will include cross-tabulation, OLS and Maximum Likelihood (ML) estimators, Kaplan-Meier survival / Nelson-Aalen hazard functions, and multivariate hazard models. Factors used in the analysis will closely mirror those described in the large literature on this topic.

In addition to analyzing the determinants of graft outcomes within the population receiving UDCD the analysis will be extended to examining graft outcomes relative to those in the DBD population. This analysis will seek to answer whether there is a graft survival benefit / equivalence in the utilization of organs from UDCD against those transplanted from other populations. Of particular interest will be the survival comparisons between the intervention group and grafts from donation after DBD that are Expanded Criteria Donors (ECDs).

(3) Cost-Effectiveness

A cost-benefit analysis will also be performed to estimate the overall social benefit from increasing the pre-hospital organ supply. By measuring the direct costs incurred during the pre-

hospital donation process, we can determine the overall cost of each kidney from UDCD used for transplant. A marginal cost comparison will reveal differences, if any, in the acquisition expenditure for an uncontrolled kidney versus that of a controlled DCD or DBD. Graft survival at 6 months will be of crucial value in determining whether or not kidneys from UDCD utilization possesses any cost advantages over standard therapy (i.e. dialysis, DBD kidney transplant).

(4) Other Analyses – Consent Rate
In order to identify areas in which the donation request for UDCD could be changed, the consent rate will undergo factor analysis. This analysis will include using the demographic and process timing data gathered by the pre-hospital team and donation request best practice implementation as documented by the FSC. Factors will include the patient's age, sex, race, ethnicity, familial relationship to the next-of-kin, and the utilization of control group best consent practices. Given the binary nature of the dependent variable, various accepted ML estimators will be utilized.

As noted previously, the conversion rate will not be solely dependent on the consent rate. Any differential between the number of consented eligible cases and the number of actual organ donors will be analyzed for areas of performance improvement. Of critical importance will be the timing of the external and internal cooling procedures in addition to artificial cardiovascular maintenance. Prolonged time intervals between these procedures leading up to the organ recovery will reduce the probability that the organs will be utilized for transplant – if recovered at all. Measures of central tendency (means and medians) for the various time intervals will be reported on a monthly basis.

Instruments

Source data gathered for this project will primarily come from the RORA team and the organ recovery personnel from NYODN dispatched to Bellevue Hospital. Instruments developed specifically for this project include the Consent Checklist for Rapid Organ Recovery (Attachment 9, Table 1) and the Flowchart for UDCD (Attachment 9, Table 2). Standard forms currently utilized according to NYODN standard operating procedure that would also be utilized in the situation of UDCD include the Donor Chart and the Medical and Social History Form. It is likely that an adaptation of the Consent for Donation form will need to be altered with the advice of legal counsel and possibly the IRB for research purposes.

These instruments may be paper-based or electronic. Existing standard forms utilized by NYODN, such as the Donor Chart, for example, are currently electronic. Confidentiality of privileged health information is of primary importance and will be maintained throughout the data gathering process.

Data for the project will be stored in a secure, firewall-equipped, local access network. Access to the database will be password-protected and limited to the investigators in the proposal. Paper forms will be stored in a secure locked medical records facility in NYODN offices.

Potential impact

From this research, we may develop an donation protocol for UDCD that may be accepted by all community stakeholders involved in organ donation structure, process, and outcomes. We may also determine that such a protocol is feasible to implement in the entire NYC EMS system. An ethical whitepaper will ensure that this and all future attempts at introducing protocols for UDCD adhere to ethical standards.

D. Work Plan

The specific project activities and key personnel responsible in the study consortium are represented in the project phases according to the Gantt Chart. The Principal Investigator, Lewis Goldfrank, MD, will submit the protocol for the studies to the institutional review board for approval. This process is expected to take 4 weeks. During this time, Dr. Goldfrank, and another member of the study team will attend the pre-implementation grant technical assistance workshop at HRSA.

Support will be sought on a professional and political level as well as on a community-based level. Drs. Goldfrank and Kaufman will work with the leadership within HHC (including Dr. Raju, MD, MBA, Executive VP, Medical and Professional Affairs, Health and Hospitals Corporation, and Salvatore Russo, Esq., Executive of Senior Council, Medical Legal Affairs) and within the Fire Department (Dr. David Prezant, Chief Medical Officer/Medical Director, Office of Medical Affairs of NYC Fire Department/EMS) to spearhead obtaining support of the City and State Commissioners of Health, the Medical Examiner, the State Attorney General, the Fire Commissioner and, if possible, the Mayor.

Eric Grossman, MD, working through the Communications Department at NYODN, in concert with a professional public relations firm, will develop the public education campaign through the involvement of community stakeholders and focus groups to test effectiveness of the campaign. Ongoing meetings and communications are expected to be conducted with transplant surgeons, FDNY EMS service personnel, organ donor counselors, policy representatives from New York State, New York City, and New York City Health and Hospitals Corporation, government agencies, ethics experts, and select representatives from non-Latino white, Latino, African American, and Asian communities. The focus groups and analysis are expected to take 6 months, while the public relations campaign will set the stage for the implementation of the program for UDCD. The UDCD protocol will be formulated in the third quarter of year one, a collaborative effort from Dr. Goldfrank (Bellevue Emergency Department), Dr. Grossman (NYODN), Dr. Teperman (NYU transplant service), Dr. Kaufman (FDNY EMS), Dr. Wall (Methodologist) and Dr. Dubler (ethicist), with Dr. Goldfrank serving as the chair of the planning committee. Once the details of the protocol are mutually agreed upon, the protocol will be brought back to focus groups of the aforementioned stakeholders for final revisions. This process is expected to take 6 months, but ongoing feedback and consultation will be sought from the grassroots communities being served. Concurrent with the protocol development, an ethical white paper, supervised by Dr. Dubler, will be published discussing the unique ethical considerations with implementing a UDCD protocol into general medical practice.

Data collection will commence in the last quarter of year 1, according to the UDCD protocol, supervised by Dr. Grossman and Fred Selck with input from Dr. Wall, and assisted by the EMS

providers who will serve as organ donor providers and data collectors. Data collection is anticipated to take two years. After the data collection commences, quantitative data analysis will ensue (last quarter of year three), supervised by Dr. Grossman and Fred Selck with input provided by Dr. Wall. In the last quarter of the study, Drs. Goldfrank, Wall and Teperman will supervise the submission of an R01 application to propose a multi-center trial in the entire NYC EMS system.

Learnings and best practices from this project will be shared with the organ donation community through National and Regional Organ Donation and Transplantation Collaborative meetings, and at meetings of the Association of Organ Procurement Organizations, and could be the basis of further IOM meetings. Three manuscripts are anticipated: a paper describing the UDCD protocol, an ethical whitepaper concerning the unique ethical considerations inherent in implementing a UDCD protocol into general medical practice, and a paper describing the results of this pilot study. Papers will be submitted to relevant transplantation and or general medical journals including *JAMA* and the *New England Journal of Medicine*. Abstracts will also be presented at conferences including the Society for Academic Emergency Medicine and the American College of Surgeons, and the American Society of Transplant Surgeons, and two members of the team will travel to the Department of Organ Transplantation at HRSA to present the findings.

Phase	**Dates**	**Activity**	**Responsible Persons**
1	9/1/07 – 10/31/07	Obtaining Administrative Support	L. Goldfrank, MD E. Grossman, MD B. Kaufman, MD
1	9/1/07 – 10/1/07	IRB Approval	L. Goldfrank, MD
1	9/1/07 – 11/30/07	Conduct Stakeholder Focus Group	E. Grossman, MD
1	12/15/07	Consortium Interim Analysis	E. Grossman, MD L. Goldfrank, MD
1	12/1/07 – 2/28/08	Analyze Qualitative Data	E. Grossman, MD S. Wall, MD F. Selck, MA
1	12/1/07 -2/28/08	Ethical White Paper	N. Dubler, LLB
2	3/1/08 – 4 /30/08	Develop Protocol	L. Goldfrank, MD L. Teperman
2	3/15/08	Consortium Interim Analysis	L. Goldfrank, MD

2	3/1/08 – 4/30/08	Develop PR Campaign	E. Grossman, MD
2	5/15/08	Consortium Interim Analysis	L. Goldfrank, MD
3	6/1/08 – 5/31/09	Implement Protocol	B. Kaufman, MD
3	9/08, 12/08, 3/08, 6/08, 9/08, 12/08	Consortium Interim Analysis	L. Goldfrank, MD

Phase	Dates	Activity	Responsible Persons
3	6/1/07 -5/31/09	Data Collection	E. Grossman, MD L. Teperman, MD
3	6/1/09 – 8/31/09	Data Analysis	E. Grossman, MD S. Wall, MD L. Teperman, MD
3	8/1 – 8/30/09	Outcomes and Evaluations Manuscript	L. Goldfrank, MD L. Teperman
3	8/1 – 8/30/09	R-01 Grant	L. Goldfrank, MD S. Wall, MD L. Teperman, MD

E. Resolution of Challenges

The main challenge in implementing an UDCD protocol in an urban setting is meeting all of the concerns of all the stakeholders involved, and perhaps foremost, ensuring the community served by the EMS providers trusts that persons will be cared for regardless of their organ donor status, especially ensuring that EMS providers will not prematurely declare death in the field to gather additional organs for transplantation.

This is a major ethical challenge for this grant. Addressing this challenge is a precondition to designing the consent process that will be comfortable for the family members donating organs, for the recipient, and for the family of the recipient. Organ donation is based on trust, most especially trust that the care team will not diminish their efforts for patient recovery because of a focus on transplantation. This is of concern to family members in the hospital but will necessarily be of greater concern in the uncontrolled situation which is far quicker and more opaque than the more transparent process in the hospital. In the hospital setting there are generally days of care before a decision about removing care is broached. This decision, and the

palliative services that should accompany it, are all precursors to the discussion and decision about donation. All of these phases of decisions, will be substantially reduced in the uncontrolled situation and must be considered in this light.

As in the case of any large and innovative new program, all stakeholders must agree on a protocol change in order to avoid engendering mistrust in the population it is intended to assist. Beginning with focus groups of all community stakeholders involved in organ donation, the investigators will generate an acceptable UDCD protocol agreed to by all stakeholders involved; however, it is conceivable that despite our efforts, the stakeholders will not achieve consensus. This outcome, which we do not envision, would preclude years two and three of the protocol. Nonetheless, information about the barriers to implementing a UDCD protocol would have been gained. The study is a pilot, intended to provide feasibility information for a multi-center trial to be conducted in the entire NYC EMS system. Given that the study will examine patients presenting to one urban academic ED, the results may not be applicable to all patient care settings but will have relevance to any city system. Future work will be done in a multi-center study in the entire NYC EMS system to validate the findings in other settings (the subject of our planned R01 submission).

The first phases of this grant will not include the actual implementation of an organ procurement and donation system. They do not fall, therefore, under a strict definition of research with human subjects. However, the project staff will be clear with persons invited to focus groups that they are under no obligation to join in the process and that transcripts and minutes of the meetings will not be identifiable by name. This will offer effective protection for non-institutional participants. Those who have organizational and institutional responsibility will be speaking for their institutions and thus their authority and responsibility are central to the discussions. The opinions of these leaders who are officers of corporations and hospital institutions or as members of city government must be moved to consensus for the project to continue to Phase 2—implementation.

If the project does move to Phase 2 there will need to be an elaborate process of informed consent for the possible recipients and their family members, at the outset and then a second elaborate process of discussion with the donor family. Potential recipients will need to agree to receipt of this organ--a process that has precedent in Europe and not in America. One of the issues to be agreed upon with the surgical teams, and perhaps with the NYODN and UNOS in Phase 1, will be the development of an expanded criterion recipient list. All of the risks, benefits and uncertainties of the process will need to be explained to the recipient. The recipient will also need to factor into the ethical calculus refusal and how that might effect time to transplant and consequently survival. This discussion will be comprehensive, many layered, multi-professional project.

Families who consider donation will need to be assured that their loved ones received the best possible care. These discussions will require careful presentation and encomiums to the process from all of the official stakeholders involved in phases 1 and 2. After this part of the discussion is successful then the more typical OPO discussion must occur. All of the draft materials and processes will be developed in phases 1 and 2.

One could argue that this new source of organs provides merely an example of an innovative process and not a matter of research that needs to be supervised by the IRB. However, we propose that the level of innovation is so distinctly different from current practice that it will be best reviewed by the IRB which commonly considers the risk/benefit ratio of research and the informed consent process.

Throughout the project, challenges may arise. The workplan indicates specific timeframes wherein the consortium leaders will conduct interim analyses and discuss challenges with the goal of resolving problems as they arise. This enables the project to be flexible and responsive to the needs identified as they arise. Continuing challenges occurring during the study will be addressed through ongoing ethics evaluation and analyses of community and staff concerns.

F. Evaluation and Technical Support Capacity

The research team consists of individuals with extensive experience in all aspects of program evaluation research methods and organ donation. The research team also has knowledge of the specific needs of the multiethnic communities and organ donation stakeholders to be studied.

Principal Investigator, Lewis R. Goldfrank, MD
Dr. Lewis Goldfrank is the Professor and Chairman of the Department of Emergency Medicine at New York University and the Director of Emergency Medicine at Bellevue Hospital Center. He is also the Medical Director of the New York City Health Department's Poison Center. His entire career has been spent working in the public hospitals of New York City. He is senior editor of *Goldfrank's Toxicologic Emergencies*. He is a member of the National Academy of Sciences Institute of Medicine where he has participated on three committees on terrorism. His investigations in preparedness include developing and leading a consortium on preparedness with the NYC Department of Health, leading the New York University School of Medicine Consortium on Preparedness. As a member of the IOM Committee on *Organ Donation: Opportunities for Action* his major role was in the development on the section expanding the population of potential donors wherein the proposal for cities of excellence for the expansion of uncontrolled DCD was described.

Co-Principal Investigator, Eric Grossman, MD
Dr. Grossman, a nephrologist, is the Medical Director of the New York Organ Donor Network. He was the Medical Director and then and group leader for cardiovascular, metabolism and sexual health at Pfizer Inc. In this leadership position, he had oversight of several teams of physicians and PhDs conducting clinical research, and had responsibility for strategic and policy initiatives, Dr. Grossman is also an attending physician at the New York Veterans Affairs Hospital and Bellevue Hospital.

Co-Principal Investigator, Bradley Kaufman, MD, MPH
Dr. Kaufman is the Deputy Medical Director for the New York City Fire Department. He oversees development of protocols for and the medical care provided by emergency medical responders in the City. In order to provide education to first responders, he frequently lectures at the Bureau of Training and at EMS Battalions. He performs research on prehospital care. Dr.

Kaufman is the department representative on various city and state committees and regulatory bodies.

Co-Principal Investigator, Lewis Teperman, MD
Dr. Lewis Teperman is the Director of the Mary Lea Johnson Richards Organ Transplantation Center at NYU Medical Center, an internationally recognized transplant program committed to unparalleled quality in its patient care, training, and research programs. In addition, he is an Associate Professor of Surgery for the New York University School of Medicine. On behalf of transplant patients and the American Liver Foundation, he was instrumental in convincing H.C.F.A. and Medicare to cover Hepatitis B patients for transplantation. Dr. Teperman helped develop and implement the new nation wide organ allocation system, MELD, specifically the HCC criteria. Dr. Teperman is active in various transplantation societies, including past Chairman of the New York Organ Donor Network (NYODN) and the Latino Organization for Liver Awareness (LOLA), as well as a past board member of the American Liver Foundation (ALF). He is actively involved in the United Network for Organ Sharing (UNOS), serving as a Board of Director, and on the Living Donor Committee. He is a past Board Member of the New York Center for Liver Transplantation (NYCLT).

Co-Investigator, Fred Selck, MA
Mr. Selck is the data analyst for the New York Organ Donor Network. Mr. Selck's advanced econometric training specific to organ donation will be used to supervise the quantitative data analysis and conduct the cost benefit analysis aspects of the research. His Masters thesis covered non-clinical determinants of receiving organ transplantation in the United States. Prior to assuming his current role, Mr. Selck's responsibilities included the allocation of organs for transplant and approaching families of potential organ donors for consent. He is a trained paramedic, and previously was a pre-hospital care provider.

Co-Investigator, Nancy Dubler, LLB
Nancy Neveloff Dubler is the Director of the Division of Bioethics, Department of Family and Social Medicine, Montefiore Medical Center and Professor of Bioethics at the Albert Einstein College of Medicine. She directs the Bioethics Consultation Service at Montefiore Medical Center (founded in 1978) as a support for analysis of difficult clinical cases presenting ethical issues in the health care setting. She is Co-Director of the Certificate Program in Bioethics and the Medical Humanities, conducted jointly by Montefiore Medical Center/Albert Einstein College of Medicine with Cardozo Law School of Yeshiva University. Her most recent books are: The Ethics and Regulation of Research with Human Subjects, Coleman, Menikoff, Goldner and Dubler, Lexis/nexis, 2005; Bioethics Mediation: A Guide to Shaping Shared Solutions, co-author, Carol Liebman, United Hospital Fund, New York, New York, 2004; Ethics On Call: Taking Charge of Life-and Death Choices in Today's Health Care System, with David Nimmons (1993); Ethics for Health Care Organizations: Theory, Case Studies, and Tools, with Jeffrey Blustein and Linda Farber Post (2002).

Methodologist/Statistician, Stephen Wall, MD, MS
Dr. Wall is an Assistant Professor of the Department of Emergency Medicine and the Department of Epidemiology and Population Health at the Jacobi Medical Center and the Albert Einstein College of Medicine. He received his Masters in Health Services Research Methods at

the UCLA School of Public Health (2003), and currently is in the Masters of Education, Communication, and Technology program at New York University. As of September 1st, 2007, Dr. Wall has accepted a faculty appointment at Bellevue Hospital and the NYU School of Medicine.

Dr. Wall received a K08 career development award through AHRQ to research multimedia educational methods to improve organ donation willingness among the multiethnic communities served by NYC hospital emergency departments. Dr. Wall currently is performing qualitative research on patients in the Bellevue Emergency Department to determine their baseline organ donation beliefs, and how these communities wish to learn more about organ donation, in a culturally sensitive manner. He and his team have extensive experience with program evaluation research methods as well as the culturally sensitivity to reach out to these underrepresented populations.

G. Organizational Information

Bellevue Hospital Center

Bellevue Hospital Center, the nation's oldest public hospital, was founded in 1736. Bellevue is a member institution of the largest public health system in the nation, the New York City Health and Hospitals Corporation. Annually, nearly 28,000 patients are discharged, and 85,000 emergency visits and over 500,000 ambulatory care visits are provided.

Bellevue Hospital Center serves a population that disproportionately includes ethnic and linguistic minority and immigrant groups who often have limited English proficiency and low health literacy. More than half the patients who seek care at Bellevue Hospital Center prefer to communicate in languages other than English. While Spanish, Mandarin, Cantonese, Polish, Bengali and French are the dominant other-than-English languages, over 60 languages are routinely requested through Bellevue's interpreting program. In New York City more than 140 languages are spoken.

Bellevue Hospital Center operates 768 beds, including 426 general care beds, 286 psychiatric beds and 56 alcohol and rehabilitation beds. Located on the eastern boundary of mid-town Manhattan, Bellevue plays a unique role among the municipal hospitals in terms of service area. While other facilities reflect a primary and secondary service area that closely surrounds the location of the hospital, Bellevue's catchment areas stretch across as many as 63 zip codes, covering large sections of 3 of the City's 5 boroughs.

New York Organ Donor Network

Founded in 1978, the New York Organ Donor Network (NYODN) is the second largest of the nation's 58 nonprofit, federally designated organ procurement organizations (OPOs). The New York Organ Donor Network is dedicated to the recovery of organs and tissues for people in need of life-saving and life-improving transplants. It is committed to increasing awareness and fostering understanding of organ and tissue donation among health care professionals and the general public. With respect and compassion, the NYODN provides individuals and their families with the knowledge required to make informed decisions about donation.

NYODN is responsible for the recovery of organs, eyes and tissues for transplantation, and public and professional education efforts for a culturally and ethnically diverse population of 13 million in the greater New York metropolitan area. The Donor Network serves Manhattan, Queens, Brooklyn, the Bronx, Staten Island, Long Island, Dutchess, Orange, Putnam, Rockland, and Westchester, and also Pike County, PA. It works closely with nine transplant centers and more than 100 hospitals.

The NYODN staff has extensive experience in developing procurement protocols, counseling families and patients, as well as conducting organ donation research projects, having completed projects with HRSA, specifically in improving organ donation rates among Asian Americans. The Donor Network is accredited by the Association of Organ Procurement Organizations (AOPO) and it is a member of the United Network for Organ Sharing (UNOS).

New York City Fire Department / EMS

When the FDNY merged with New York City Emergency Medical Services (EMS), the largest fire department-based EMS in the country was created. Implementation of the Certified First Responder Defibrillator (CFR-D) program has helped create a true, three-tiered emergency medical system in New York City. CFR-D is the first and basic level of training, followed by Basic Life Support and then Advanced Life Support.

Studies by the American Heart Association have shown a dramatic increase in the survival rates for out-of-hospital cardiac arrest victims who have quick and efficient CPR and defibrillation, followed by rapid access to the 911 system. This tiered response has generated a downward trend in response times and saved the lives of countless New Yorkers.

In 2006, FDNY EMS responded to 1,152,109 incidents, of which 408,451 were categorized as segment 1, 2, or 3 (the most life-threatening medical emergencies such as cardiac arrest and major trauma). Combined EMS and CFR-D average response time to segment 1 to 3 incidents was five minutes and 49 seconds, a decrease of more than two minutes compared to 1995, the year before the Fire Department EMS merger.
Municipal and voluntary hospital emergency response units are dispatched and operate under the authority of the FDNY.

The FDNY recently participated in the PHENYCS study (Pre-Hospital Evaluation of New York's Cardiac Survival), which was designed to assess the survival rates of victims who suffered cardiac arrest in NYC and compare those rates to a similar study conducted 10 years ago. For the study period (April 1, 2002 to March 31, 2003), data was collected on 6,973 adult patients who suffered an out-of-hospital cardiac arrest. From 1990 to 1991, the survival rate for patients suffering from cardiac arrest was 2.2 percent. That figure rose to 3.1 percent – an increase of 40 percent – despite an increasingly aging population in the City. The FDNY has continued to focus on improving survival from out-of-hospital cardiac arrest and is currently leading an international trial of a new defibrillator technology called SmartCPR.