

PI: Goldfrank, LR
Attachment 1

Staffing Plan

Phase I – Building Support

.2 FTE – Principal Investigator/In-Hospital Coordinator
.1 FTE – Co-PI/Organ donation Coordinator
.1 FTE – Co-PI/Transplant Surgeon
.1 FTE – Co-PI/Pre-Hospital Coordinator
.05 FTE – Ethicist
.2 FTE – Data Analyst
In Kind – Methodologist/Statistician

Phase II – Develop Protocol, Interim Qualitative Analyses, develop Public Education Campaign

.2 FTE – Principal Investigator/In-Hospital Coordinator
.1 FTE – Co-PI/Organ donation Coordinator
.1 FTE – Co-PI/Transplant Surgeon
.1 FTE – Co-PI/Pre-Hospital Coordinator
.05 FTE – Ethicist
.2 FTE – Data Analyst
In Kind – Methodologist/Statistician

Phase III – Implement Protocol, Data Collection and Quantitative Analysis

.2 FTE – Principal Investigator/In-Hospital Coordinator
.1 FTE – Co-PI/Organ donation Coordinator
.1 FTE – Co-PI/Transplant Surgeon
.1 FTE – Co-PI/Pre-Hospital Coordinator
.05 FTE – Ethicist
.2 FTE – Data Analyst
In Kind – Methodologist/Statistician
4 FTE – Emergency Medical Technicians
2 FTE – Family Service Coordinators

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Project Objective	Key Staff	Effort	Justification
Develop Administrative commitment	L. Goldfrank, MD L. Teperman, MD B. Kaufman, MD E. Grossman, MD	4 hrs/week per member for 4 weeks.	It is anticipated that there will be 2 meetings weekly (approximately 2 hours each for 4 weeks with City and State officials to address issues of presumed consent.
Conduct Stakeholder Focus Groups	E. Grossman, MD	4 hrs/week per member for approximately 6 weeks.	Focus groups will be conducted with key stakeholders to assess attitudes about organ donation. The focus groups will be organized by the Organ Donor Network which has extensive experience in this area.
Obtain grassroots support.	E. Grossman, MD	4 hours per week each for approximately 6 weeks.	Focus groups will be conducted with Community Organizations and community representatives to assess attitudes about organ donation and to obtain information about how to develop the public education effort. The focus group will be led by the New York Organ Donor Network in collaboration with an experienced public relations consultant.
Analyze Qualitative Data	E. Grossman, MD. F. Selck, MA S. Wall, MD	4 hours per week for 12 weeks. 8 hours per week for 12 weeks. In kind contribution.	Both descriptive and statistical analyses will be performed based on data from focus groups.

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Project Objective	Key Staff	Effort	Justification
Prepare Ethical White Paper	N. Dubler, LLB	2 hours per week for 12 weeks.	A total of 24 hours will be devoted to integrating the information from the focus groups to formulate an ethical white paper.
Develop UDCD Protocol Based on Focus Groups	L. Goldfrank, MD N. Dubler, LLB E. Grossman, MD B. Kaufman, MD L. Teperman, MD	8 hours/ week 2 hours/week 4 hours/week 4 hours/week 4 hours/week	Based on input from focus groups, the protocol will be developed by the consortium. This is expected to take approximately 8 weeks, with the last three 3 weeks devoted to achieving consensus from all stakeholders and obtaining political support to proceed with the pilot.
Develop Public Education Campaign	E. Grossman, MD	4 hours per week for approximately 8 weeks.	In consultation with a professional PR firm, public education awareness materials and strategy will be developed.
Implement Protocol	4 EMTs 2 FSCs B. Kaufman, MD L. Teperman, MD	8 hours per day, 7 days per week for 24 months. 4 hours per week for 24 months.	Based on current design, the pilot will operate for 2 years, one shift per day, 7 days per week. Staff will respond to every organ donation opportunity during that shift.
Collect Data	FSCs EMTs	8 hours per day, 7 days per week for 24 months.	When there is no organ donation opportunity, staff will be used to collect data and provide public information.

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Project Objective	Key Staff	Effort	Justification
Prepare Outcomes and Evaluations	L. Goldfrank, MD. E. Grossman, MD B. Kaufman, MD L. Teperman, MD	8 hours per week for 4 weeks. 4 hours per week. 4 hours per week. 4 hours per week.	Based on the data analysis, the key consortium members will evaluate the pilot and develop recommendations for future efforts.

Position Descriptions

Principal Investigator, Lewis R. Goldfrank, MD: Inhospital Coordinator

Lewis R. Goldfrank will be the principal investigator responsible for obtaining Hospital and City administrative and political support. He will be responsible for obtaining IRB approval and conducting interim analyses which will lead to the definitive protocol development. He will be responsible for leading outcomes analysis and developing the evaluation manuscript.

Qualifications

Lewis Goldfrank is the Chairman of Emergency Medicine at New York University with extensive administrative and investigative experience.

Co-Principal Investigator, Eric Grossman, MD: Organ Donation Coordinator

Eric Grossman will share responsibility for obtaining administrative support from the organ donor community while conducting stakeholder focus groups. He will participate in data collection, and consortium interim quantitative and qualitative analyses. He will develop a public education and relations campaign.

Qualifications

Eric Grossman is the Medical Director of the New York Organ Donor Network with extensive leadership, administrative and investigative experience in organ donation.

Co-Principal Investigator, Bradley Kaufman, MD, MPH: Prehospital Coordinator

Bradley Kaufman will obtain administrative support from the EMS and Fire Department communities – including NYC and New York State agencies. He will be the lead person in implementing the field aspects of the protocol. He will monitor the prehospital aspects of the protocol and participate with criterion analysis review.

Qualifications

Bradley Kaufman is the Deputy Medical Director for the New York City Fire Department with extensive prehospital leadership and investigative experience.

Co-Principal Investigator, Lewis Teperman, MD: Transplant Surgeon

Lewis Teperman will be a thought leader in the protocol development, interim analysis and team development. His knowledge of transplantation standards will be essential throughout and will be particularly pertinent in data collection and analysis. He will participate in long term research design.

Qualifications

Lewis Teperman is the Director of New York University Organ Transplant Center with extensive involvement in patient care, training and research.

Co-Investigator, Fred Selck, MA: Data Analyst

Fred Selck will supervise data analysis and conduct benefit analysis for the project.

Qualifications

Fred Selck is extensively trained in econometrics specific to organ donation

Co-Investigator, Nancy Dubler, LLB: Ethicist

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Nancy Dubler will be responsible for the development of ongoing ethical analysis of the project. She will review subgroup needs with regard to cultural and religious concerns. She will develop an ethical White Paper based on the project design, dilemmas and implementation.

Qualifications

Nancy Dubler is the Director of the Division of Bioethics and Professor of Bioethics at the Albert Einstein College of Medicine.

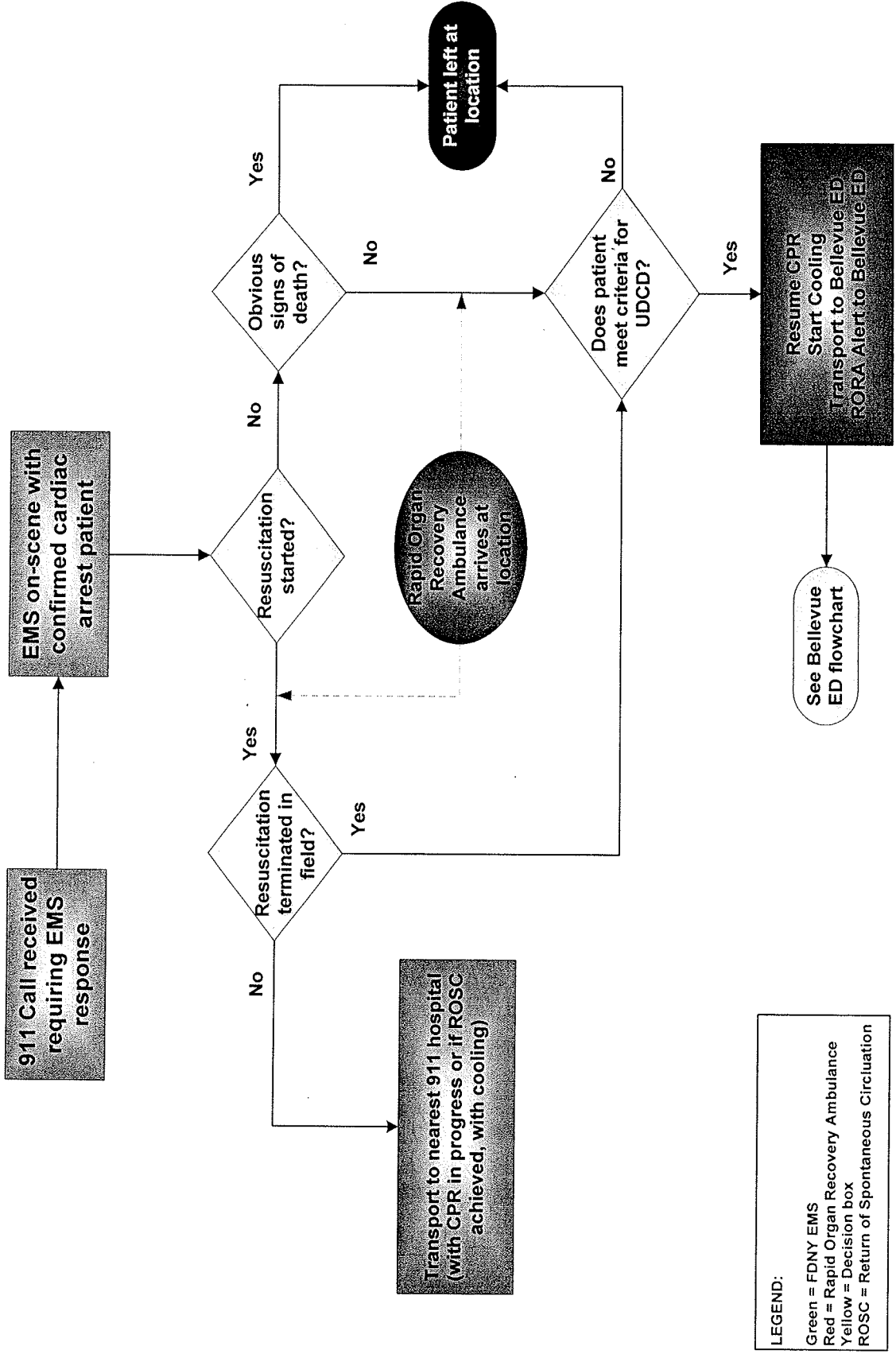
Methodologist/Statistician, Stephen Wall, MD, MS: Methodological Statistician

Stephen Wall will analyze qualitative and quantitative data while reviewing all aspects of methodology. He will assist in focus group development and analysis. He will subsequently develop long term research goals in this domain.

Qualifications

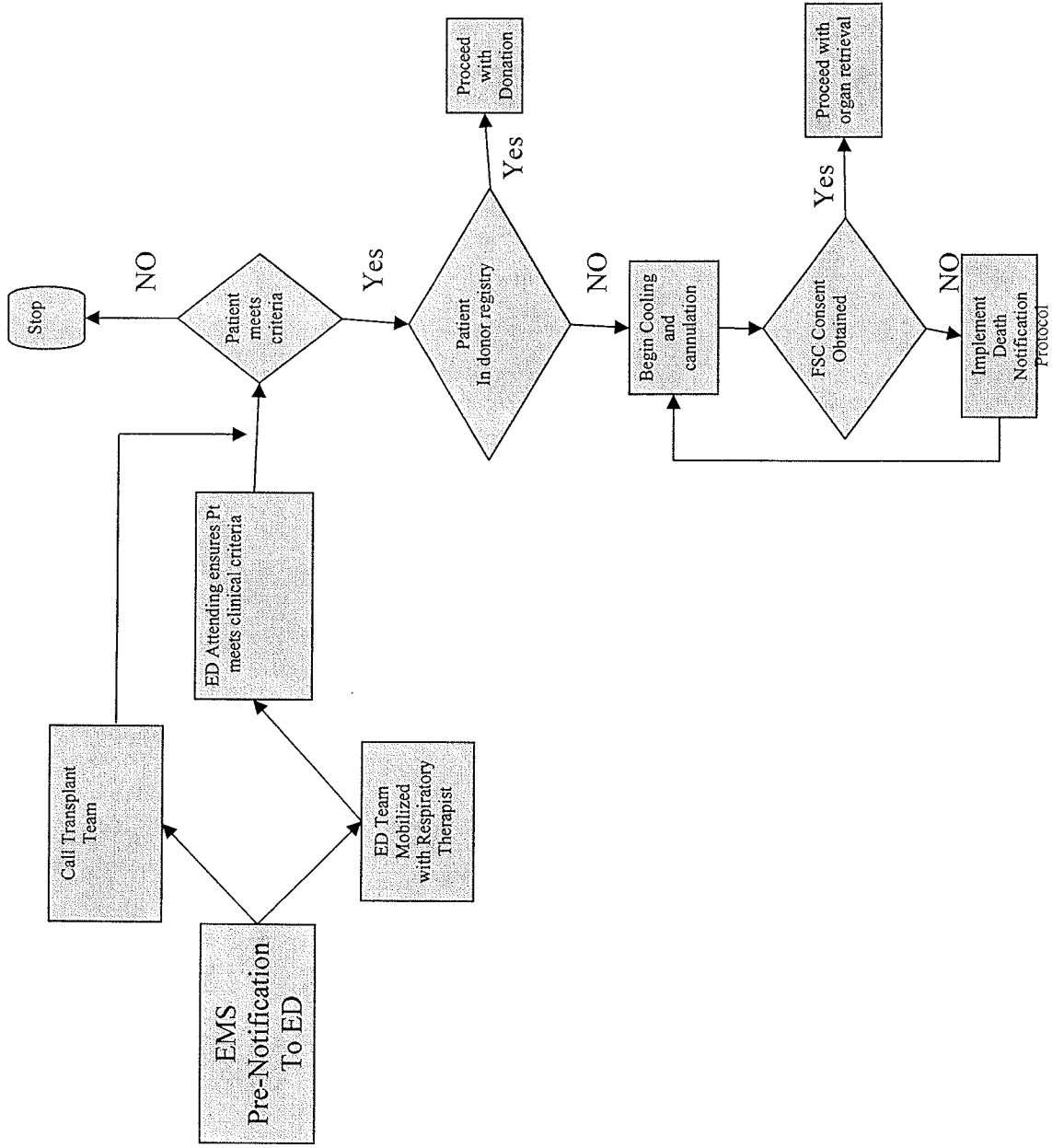
Stephen Wall is an Assistant Professor of Emergency Medicine at the Albert Einstein College of Medicine with Masters training in Health Sciences Research Methods and is currently studying for a Masters in Education, Communications and Technology.

EMS Prehospital Flowchart



LEGEND:
Green = FDNY EMS
Red = Rapid Organ Recovery Ambulance
Yellow = Decision box
ROSC = Return of Spontaneous Circulation

In Hospital Process



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Attachment 8

Job Descriptions

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Stephen Wall will analyze qualitative and quantitative data while reviewing all aspects of methodology. He will assist in focus group development and analysis. He will subsequently develop long term research goals in this domain.

Qualifications

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New York Organ Donor Network		
Consent Checklist for Rapid Organ Recovery		
Patient Name		
Family Services Coordinator		
Time of identification of Next-of-kin		
Time when interaction with family was started		
Time when donation request was made		
Time when an answer was received from the family		
Variable	Description	Yes / No
Pre-Approach	A pre-hospital or hospital staff member asks the family to donate organs or tissue	
Pre-mention	A pre-hospital or hospital staff member mentions the possibility of organ or tissue donation to the family	
Engaged in a collaborative communication plan between NYODN staff and the hospital	Any collaboration between the FSC and hospital about a plan or course of action	
Family initiated discussion of donation	If the family were the first ones to bring up donation without being asked by NYODN or hospital personnel	
Request made in an appropriate place	The approach was not made at the bedside or in a hallway	
Appropriate introduction to the family	The hospital introduces NYODN staff without mentioning donation	
Did the requestor have sufficient time to prepare?	The requestor felt that there was sufficient time to prepare prior to making the request.	
Huddle initiated by OPO staff	This question addresses whether or not NYODN staff initiated the huddle process.	
Telephonic approach	The request for donation was made over the phone.	
Requested donation from NOK in a foreign country	NOK was approached telephonically while in a foreign country	
Third party request	An interpreter was used to make the donation request	
Requestor expressed condolences prior to the donation request	The requestor expressed condolences to the family prior to making the donation request	
Engaged family in conversation about their loved one	The requestor asked probing questions about their loved one.	

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Ensured a positive transition to donation during the family conference	A positive transition was made to organ and tissue donation by the requestor.	
Recipient-centered discussion	The requestor has made comments about the number of people waiting on the list, etc.	
Empowering Ask	As defined by the Dual Advocacy approach. To be assessed by those entering the data.	
Re-Approach	Was the next-of-kin asked more than once to donate?	
Documented wishes that the patient did not want to donate	Actual documentation (healthcare proxy, etc.) stating that the patient did not want to be a donor.	
Were objections to donation addressed?	Marked only if objections arose. Yes if the requestor addressed objections, No if the requestor did not.	
Appropriate NOK identified	Did the FSC identify the NOK correctly?	
Was consent obtained for any organs?	Self-explanatory	
Was consent obtained for any tissue?	Self-explanatory	
Did they have early intervention and give continuous support to the family?		

Budget Narrative
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Bellevue Budget Justification Year 1

During the first year, resources will be allocated for securing political and community support for the projects as well as for developing the protocol. This will take approximately nine (9) months to accomplish. The last quarter of the project year will be implementation of the protocol.

Personnel Costs:

Lewis Goldfrank, MD, Principal Investigator, Salary \$186,600
20% Effort

Dr. Goldfrank is a member of the Institute of Medicine and was a committee member responsible for conceptualizing how pursuing donations after cardiac death is a feasible approach to increase organ donations, based on evidence from other countries and on data obtained through NYC EMS. He will oversee the all the operations associated with this proposal.

Stephen Wall, MD, MS Methodologist/Statistician Salary: in kind.
As Needed

Dr. Wall is a health services researcher funded through an AHRQ K08 career development award to develop novel approaches using multimedia to improve enrollment into online organ donor registries (Dr. Goldfrank is the organ donation expert serving on his committee of mentors). As part of his research, he is conducting qualitative assessments of emergency department patients in the Bellevue Emergency Department to better understand all multiethnic opinions surrounding organ donation. Dr. Wall will provide the results of his research to the study team in year one, supplementing the needs assessments. Dr. Wall will also consult on all the methods and statistical analysis necessary for project completion.

Lewis Teperman, MD, Co-Investigator, Salary \$186,600
10% Effort

Dr. Teperman is the Chief and Director of Transplantation Surgery at NYU Medical Center, the service provider to Tisch Hospital and Bellevue Hospital. Dr. Teperman will supervise the development of protocols to ensure procured organs from donors determined to have died from circulatory causes are viable for transplant recipients. He will also supervise the hospital protocols for procuring the organs from donors, working with the NYODN per established guidelines.

Fringe Benefits:

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The fringe benefit rate at Bellevue is 31%. This includes health insurance, taxes, unemployment, disability, life, and medical insurance, a retirement plan and tuition reimbursement.

Travel:

Dr. Goldfrank along with another study team member will travel twice to Washington D.C. for the technical assistance workshops in year one. Round trip on AMTRAK from NYC to Washington DC is \$300 per person totaling \$1,200 for the two team members. The Washington D.C. per diem rate including meals and hotels is \$256 per day per person. Based on two people traveling for two days this totals \$1,024. The remaining \$276 will cover possible fare changes in AMTRAK, and travel to and from the area train stations. This is the rationale for the \$2,500 travel budget item in year one.

Equipment:

An Auto pulse CPR Device at \$19,000 will be purchased for in-hospital use. The device will be used to prepare the donor for organ retrieval and will allow the EMS crew to return to the field, should there be another call.

Subcontracts:

There will be \$316,758 in subcontracts to the consortium members in the first year (see their detailed budget justification).

Montefiore Budget Justification Year 1

Personnel:

Nancy Dubler, MD, Co-Investigator, Salary \$154,741
5% Effort

Dr. Dubler is a bio-ethicist with vast experience and interest in organ donation. She will oversee that all the operations and protocols associated with this proposal adhere to ethical standards and will draft a white paper regarding unique ethical considerations associated with procuring organs from those with circulatory determinations of death. She will also participate in the qualitative data gathering and analysis phase of the project as participate as an ethical advisor to the consortium members throughout the duration of the project.

Indirect Costs:

The Federally negotiated off site rate for Bellevue Hospital Center is 14.32%. This indirect rate is applied to all direct costs attributed to this site.

Fringe Benefits:

The fringe benefit rate at Montefiore is 32%. This includes health insurance, taxes, unemployment, disability, life, and medical insurance, a retirement plan and tuition reimbursement.

NYODN Budget Justification Year 1

Personnel Costs:

PI: Goldfrank, LR

Eric Grossman, MD, Co-Principal Investigator, Salary maximum \$186,600
10% Effort

Dr. Grossman is the Medical Director for the New York Organ Donor Network, having extensive research experience as an academician and researcher for Pfizer Pharmaceuticals. Dr. Grossman will supervise all the methodology and statistical aspects of this research as well as infrastructure and support necessary for changing organ donation policy. Dr. Grossman will also supervise the public relations components of the protocol.

Fred Selck, Data Analyst, Salary \$72,000 20% Effort

Throughout the project period, a data analyst at 20% effort will be allocated to collect all the necessary information regarding the organ donation, procurement, and the transplant outcomes resulting from the program, specifically in regards to organs donated after circulatory determination of death. The data analyst will also be responsible for maintaining the study database, performing summary statistics, and assisting with results reporting for both qualitative and quantitative data portions of the project.

TBA, FSCs (2 organ donor counselors), Salary \$72,000 per FSC
100% Effort

Two dedicated full time organ donor counselors will be allocated to the new emergency medical services ambulance, to recruit patients as potential organ donors. The counselors will be stationed in the firehouse, where the special organ donor unit will be stationed. The counselors will be on one tour a day, 7 days a week. To allow for vacation days and or sick leave, the NYODN, will allocate their other counselors on an as needed basis to ensure the unit is always staffed with a counselor. The counselors will provide emotional support to families of patients who are in cardiac arrest or determined to have died from cardiac arrest at the scene. For those patients whom are determined dead at the scene by standard EMS protocols, the counselors will counsel the family about organ donation in addition to grief counseling. For those patients whom the family agrees to donation, the counselor will assist the paramedics with initiating the appropriate cooling measures and use of the automated CPR device. The counselors will also initiate the donation after cardiac death protocols by notifying Bellevue Hospital staff of the impending donation.

Indirect Costs:

The Bellevue Hospital Center indirect cost rate of 14.32% and will be applied to all costs.

Fringe Benefits:

The fringe benefit rate for the NYODN is 28%. This includes health insurance, taxes, health and life insurance, and a retirement plan.

Consultants:

A public relations/market research firm will be hired to conduct focus groups and to develop a public education strategy and materials. The focus groups will be conducted among transplant surgeons, New York City and State elected and appointed leaders along with their legal representatives, emergency medical services personnel (FDNY), New York Organ Donor Network counselors and administrators, Bioethicists, and community stakeholders including non-Latino whites, Latinos, African Americans, and Asians. It is anticipated that 10 groups will

be assessed, and the research will include recruitment, facilitation, taping, transcription, analysis and results reporting. The public relations effort will be based on results from the market research studies. We project this advertising effort will cost \$100,000 in year one. The NYODN will also supplement this endeavor with current advertising funds available for their current advertising campaigns.

FDNY/EMS Budget Justification Year 1

Personnel:

Brad Kaufman, MD, Co-Principal Investigator, Salary \$150,000
10% Effort

Dr. Kaufman is a Deputy Medical Director for the NYC Fire Department, responsible for the EMS provider protocols. He will facilitate the protocol adherence, policy, and data collection from the EMS providers. He will also be responsible for maintaining the CPR, cooling, and other necessary equipment associated with the project. Dr. Kaufman will also serve as the liaison between the study team and the EMS providers to ensure prehospital protocols are followed. The annual cost of his effort including fringe is \$19,500.

To cover 1 8-hour shift, 7 days weekly for a 2-person ambulance crew requires 4 EMTs @ an annual salary of \$29,296 each. The three-month cost would be \$38,084 (including fringe).

Indirect Costs:

The Federally negotiated off site rate for Bellevue Hospital is 14.32% and will be applied to all FDNY/EMS costs.

Fringe Benefits:

The fringe benefit rate at FDNY is 30%. This includes health insurance, taxes, unemployment, disability, life, and medical insurance, a retirement plan and tuition reimbursement.

Equipment:

In the 4th quarter of the first year, the pilot will be implemented. The necessary equipment needs to be purchased. 2 Horsby cooling garment kit (Arctic Heat Inc.) to preserve organ function from potential donors will be purchased along with maintenance agreements. The estimated cost per kit is \$10,000 per kit for a total of \$20,000.

An AutoPulse CPR device will be purchased, allowing the paramedics to concentrate on other organ preserving activities as well as to focus on driving to Bellevue without compromising motorist safety. This device also requires maintenance as well as purchasing additional disposable belts to conduct CPR. The device, maintenance agreement and additional belts are projected to cost \$15,000 as estimated by quotes.

A transport ventilator is required to maintain ventilation and oxygenation of the potential organ donor during transport to the Emergency Department. The device and maintenance are projected to cost \$10,000.

Other:

An EMS unit will be rented for two years, spread from the 4th quarter of year one through the 3rd quarter of year 3. The unit costs \$178,220 with an expectancy of 5 years, thus a charge of \$35,644 per year for the unit, or \$8911 per quarter for the two year intervention period.

Initial outfitting of an ambulance includes other OTPS equipment/supplies (as listed in the Equipment Attachment) and typically costs \$16,000 for the five year life of an ambulance. For a three-month rental, this would cost approximately \$800.

Other direct costs include contractual agreements for EMTs – including meal allowance @ \$1009 per EMT per year and \$130 per EMT per year uniform allowance. We also include projections for overtime in case the ambulance is with a potential donor when the shift ends or for additional coverage should unanticipated absenteeism occur among the crew scheduled to work. We assumed, on average, 1 hour of potential overtime daily. For a 2 person crew, that would be 14 hours per week or 168 hours for the three-month period. If each EMT earns approximately \$18.71 per hour, an overtime factor of 1.5 yields an overtime rate of \$28.07 per hour of overtime @ 168 hours yields approximately \$4715 in potential overtime costs.