FIRE DEPARTMENT

9 METROTECH CENTER BROOKLYN, N.Y. 11201-3857

BUREAU OF LEGAL AFFAIRS

December 26, 2008

Ms. Jenny Small
Judicial Watch
501 School Street, SW
Suite 725
Washington, DC 20024

Re: Our File No.: 07-061-08F

Dear Ms. Small:

We are in receipt of your payment in the amount $53.50 (214 pages @ $0.25 per page, which you submitted in response to my letter dated November 26, 2008. Enclosed please find the documents (214 pages) responsive to your request.

Sincerely,

Maura J. Kugelman
Records Access Officer

FDNY Budget Justification

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.

Indirect Costs:
The Federally negotiated off site rate for Bellevue Hospital is 14%, and will be applied to FDNY, as FDNY is a partner with the New York City Health and Hospitals Corporation, which Bellevue is a member.

Fringe Benefits:
The fringe benefit rate at Bellevue is 31%. This includes health insurance, taxes, unemployement, disability, life, and medical insurance, a reritement plan and tuition reimbursement.

Equipment:
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 from quotes given to Jacobi Hospital Center and from Internet articles describing the technology).

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.

2 Horsby cooling garment kit (Arctic Heat Inc.) to preserve organ function from potential donors will be purchased along with maintanence aggrements. The estimated cost per kit is $10,000 per kit for a total of $20,000.

Other:
An EMS unit will be rented for two years, spread over the 1st quarter of year one, through the 3rd quarter of year 3. The unit costs $178,212 with an expectancy of 5 years, thus a charge of $35, 642 per year for the unit totals $71, 284.80 for the two year intervention period. The staffing for the unit (one eight hour tour a day, seven days a week, with overtime protection) costs $145,971. This figure was adjusted with the 14% indirect rate. Thus, in year one, $40,204 (for ¼ year), in year two, $160,815 (all of year 2), and in year three, $125,436 (for ¾ year) will be charged to the study for rental of the unit. The EMS providers, however serve as data collectors as well as

providers for this study, and most of the time will be spent in this research capacity, as there are only at most 100 cardiac arrests annually within Bellevue's catchment area annually.

THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

OFFICE OF THE COMMISSIONER

125 WORTH STREET, CN-28
NEW YORK, NY 10013
NYC.GOV/HEALTH

THOMAS R. FRIEDEN, M.D., M.P.H.
COMMISSIONER
TEL (212) 788-5261
FAX (212) 964-0472

August 6, 2007

Lewis R. Goldfrank, M.D.
Professor and Chair, Emergency Medicine
Medical Director, New York City Poison Center
Bellevue Hospital Center
Department of Emergency Medicine
462 First Avenue, Room OBV-345A
New York, NY 10016

Dr. Goldfrank,

Thank you for your June 15 letter regarding organ donation and for sending a copy of the IOM report. Increasing and improving organ donation is an important goal and I hope HRSA awards you and your team the grant for which you applied.

Although the Health Department has no specific program or resources to offer to organ donation efforts, I hope you will keep us informed of key developments in your efforts.

Best wishes,

Thomas R. Frieden, M.D., M.P.H.
Commissioner

MEMORANDUM OF UNDERSTANDING
BETWEEN BELLEVUE HOSPITAL/HHC AND
THE NEW YORK CITY FIRE DEPARTMENT
FOR THE IMPLEMENTATION OF
THE ORGAN DONATION GRANT

MEMORANDUM OF UNDERSTANDING made as of this 1st day of September, 2007, by and between BELLEVUE HOSPITAL CENTER ("Bellevue"), a member facility of the NEW YORK CITY HEALTH AND HOSPITALS CORPORATION, a public benefit corporation organized under the laws of the State of New York, with its principal offices located at 125 Worth Street, New York, New York 10013, and THE CITY OF NEW YORK, a municipal corporation organized under the laws of the State of New York, by and through the NEW YORK CITY FIRE DEPARTMENT ("FDNY"), with its headquarters located at 9 MetroTech Center, Brooklyn, New York 11201-3857.

WITNESSETH:

WHEREAS, Bellevue Hospital, located in Midtown Manhattan, is a leading medical center serving the people of New York City, and participates in regional, state and national organ donation networks; and

WHEREAS, the New York City Fire Department, a New York State-licensed ambulance service, provides pre-hospital emergency medical treatment and transport ("emergency ambulance service") to the people of New York City through the New York City 911 System; and

WHEREAS, organ transplantation offers the opportunity to improve the health or save the lives of individuals whose own organs are failing and who would otherwise

suffer illness or death, but there are insufficient numbers of organ donors to meet the need for organ transplants; and

WHEREAS, studies have shown that extending the organ donation process, which is currently limited to the hospital setting, to the pre-hospital environment may dramatically increase organ donation, provided that organ viability can be maintained pending transport of the deceased to the hospital; and

WHEREAS, Bellevue Hospital, FDNY and the New York Organ Donor Network ("NYODN") formed a consortium to develop a grant proposal to enhance the opportunity for organ donation from New York City 911 System patients who suffer cardiac arrest under certain circumstances; and

WHEREAS, the grant proposal that was developed and submitted resulted in the award to Bellevue, by the Human Resources and Services Administration of the United States Department of Health and Human Services, of a grant entitled "Opportunities for Organ Donation: Expanding the Right to Donate Organs Following Uncontrolled Circulatory Determination of Death (the "Grant"), which provides funding for an investigation of the opportunities for organ donation following cardiac death, and which names FDNY and NYODN as Co-Principal Investigators; and

WHEREAS, the Grant consists of three phases, a first phase involving the development of a consensus among stakeholders on the need for, and approach to, a donation program for out-of-hospital cardiac deaths ("Phase I"), a second phase, based on the results of Phase I, involving development of the final medical protocol for donation and a public education campaign, and provided the goals of Phases I and II are achieved, a third phase involving the implementation of a pilot program to identify potential organ

donors and to develop the means to preserve their organs for donation in the pre-hospital environment ("Phase III"),

NOW, THEREFORE, it is agreed between the parties to this Memorandum of Understanding, as follows:

1. Areas of Collaboration. The parties agree to collaborate upon procedures and protocols to achieve the goals of the Grant, including but not limited to:

(a) Consultation with stakeholders, including the New York State Department of Health, New York City Law Department, Office of the New York City Chief Medical Examiner, and religious and community organizations, regarding the legal, ethical and cultural issues arising from organ donation in the pre-hospital environment, and the development of procedures and protocols by which deceased cardiac patients may be removed by 911 System ambulances to hospitals for possible organ donation, consistent with the resolution of such issues.

(b) Subject to Paragraph 2 of this Memorandum of Understanding, development of procedures and protocols for the implementation of Phase II of the Grant, including:

(1) Development of procedures and protocols for the designation of a Rapid Organ Recovery Ambulance ("RORA") to initiate organ preservation and for hospital transport of the deceased.

(2) Development of criteria to be used to identify potential donor candidates and documentation of donor and recipient outcomes.

(3) Development of procedures and protocols to ensure that the pilot program is culturally and linguistically appropriate to the community

served by the Grant, and that all services provided pursuant thereto are accessible to persons with disabilities.

(c) Development of procedures and protocols for the collection and analysis of data and information from donors and recipients. The parties will cooperate in the exchange of data and information necessary to meet the Grant goals consistent with laws, rules and regulations applicable to the sharing of protected health information, including the Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164) adopted by the United States Department of Health and Human Services to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA Regulations).

(d) Development of guidelines for disclosure or publication of any reports, data and other information relating to the Grant, including market research, white papers, protocols and procedures, processes, research and writings. For purposes of such disclosure, the parties shall establish and convene a "Publication Committee," composed of an equal number of representatives of each party, which shall approve the form, format, and content of materials to be disclosed. All published materials shall acknowledge the parties to this Memorandum of Understanding, and their participation, as well as the generosity of the donors and donor families, where appropriate. Ownership and control of any publications, innovations, procedures or other material benefit derived from the Grant shall be jointly and equally owned by the parties and shall be acknowledged in any such publication or disclosure.

(e) Identification and designation of staff responsible for quality assurance, exchange of patient information and data, education and training of personnel, and outreach and public awareness.

(f) Attendance at planning meetings convened to implement the Grant and achieve its goals.

2. Phasing of Grant. The parties shall not proceed with Phase III of the Grant unless and until each of the parties to this Memorandum of Understanding agrees that the goals of Phases I and II have been achieved, and that there is a consensus among the parties, the New York City Law Department, the Office of the Chief Medical Examiner, and other stakeholders, that the legal and other concerns raised by the grant have been satisfactorily addressed.

3. Bellevue Responsibilities. Bellevue shall specifically undertake the following responsibilities:

(a) Administration of the Grant, including reimbursement of FDNY for Grant and related expenses (Phases I, II and III).

(b) Use of its Emergency Department equipment, supplies and staff for organ donor candidates (Phase III).

(c) Use of its operating room equipment, supplies and staff for organ recovery (Phase III).

(d) Coordination with the Chief Medical Examiner's Office for candidates deemed ineligible for organ donation (Phase III).

4. FDNY Responsibilities. FDNY shall specifically undertake the following responsibilities:

(a) Supply the RORA for one eight-hour tour, seven (7) days a week (Phase III).

(b) Staff the RORA with two (2) Emergency Medical Technicians (Phase III).

(c) Authorize the participation of the Co-Principal Investigator approximately four hours per week and/or other appropriate FDNY staff (Phases I, II and III).

(d) Participate in data collection (Phases, I, II and III).

5. No Joint Venture. The understanding of the parties set forth herein shall not be construed to be a joint venture. The determination to implement such procedures or protocols as may be developed to achieve the goals of the Grant lies with each party, and each party is and shall remain solely responsible for such determination. Nothing contained herein shall be construed to make either party responsible for the other party's acts or omissions in implementing such procedures or protocols.

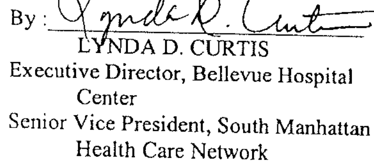
6. Reimbursement for Services. FDNY shall submit monthly invoices to Bellevue, as Grant administrator, for FDNY professional and staff time, materials, RORA operations, approved subcontractors, and any other expenses reasonably incurred in connection with the implementation of the Grant.

7. Equal Employment Opportunity Compliance. The parties agree that they shall not unlawfully discriminate on the basis of race, creed, color, sex, national origin, sexual orientation, marital status, citizenship status or disability, and shall comply with all applicable Federal, State and City laws rules and regulations in the delivery of any services pursuant to this Memorandum of Understanding.

8. Effective Date, Term and Termination. This Memorandum of Understanding shall take effect as of the date first written above, and shall remain in effect until the expiration of the Grant or the completion of work authorized by the Grant, whichever is later, unless this Memorandum of Understanding is sooner terminated. Either party may terminate this Memorandum of Understanding without cause upon ninety (90) days written notice to the other party, or forthwith, for cause, upon written notice to the other party. Cause for termination shall include any violation of law, intentional misconduct, gross negligence, violation of the terms of the Grant, or violation of the terms of this Memorandum of Understanding, relating to the obligations of the parties pursuant to the Grant and this Memorandum of Law.

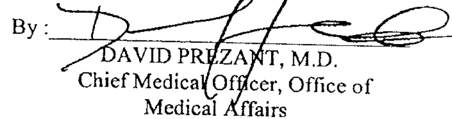
IN WITNESS WHEREOF, duly authorized representatives of the parties have executed this Memorandum of Understanding in duplicate as of the date first set forth above.

BELLEVUE HOSPITAL CENTER

By: 
LYNDA D. CURTIS
Executive Director, Bellevue Hospital Center
Senior Vice President, South Manhattan Health Care Network

Date: 6/3/08

NEW YORK CITY FIRE DEPARTMENT

By: 
DAVID PREZANT, M.D.
Chief Medical Officer, Office of Medical Affairs

Date: 4/18/08

INSTITUTE OF MEDICINE

MEETING SUMMARY • DECEMBER 20, 2006

MOVING FORWARD IN INCREASING ORGAN DONATION: OPPORTUNITIES AND BARRIERS TO UNCONTROLLED DCDD IN MAJOR METROPOLITAN CITIES

On December 20, 2006, the Institute of Medicine (IOM) held a meeting focused on disseminating the recommendations of the IOM report, Organ Donation: Opportunities for Action with particular attention to the next steps regarding uncontrolled donation after circulatory determination of death (DCDD). The meeting addressed opportunities and barriers for building public and professional consensus and implementing uncontrolled DCDD programs in major metropolitan areas. Three cities (Chicago, New York City, and Washington, D.C) served as examples for discussion. Participants in the meeting (listed at the end of this summary) included transplant surgeons, emergency response personnel, hospital administrators, emergency care professionals, organ procurement organization (OPO) staff, ethicists, and health policy and government representatives. In accordance with IOM policy on dissemination meetings, all statements in this summary are attributed to specific speakers, and the summary does not contain additional IOM recommendations.

Jim Childress and Jim DuBois co-chaired the meeting and, building on the IOM report, introduced uncontrolled DCDD as an opportunity to significantly increase the potential number of organs for transplantation and to provide an option for donation to greater numbers of individuals. Dr. DuBois asked the group to consider the issues relevant to the feasibility of uncontrolled DCDD and whether uncontrolled DCDD is equally feasible to organ donation after neurologic determination of death (DNDD or "brain death").

OVERVIEW OF THE ISSUES

Lewis Goldfrank opened his presentation with an overview of the issues by reminding the group that many people who die never have the opportunity to be organ donors.

In reviewing the common forms of donations, he noted that there are approximately 7,000 living donations of single organs each year. Neurological determination of death accounts for approximately 23,000 transplanted organs annually from just over 7,500 DNDD donors, although the potential exists for 12,000 to 16,000 DNDD donors. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations. Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

Dr. Goldfrank noted the need for clearer terms and definitions, for instance, in the categorization frameworks, such as the Maastricht categories. He stressed the difficulties in defining and distinguishing controlled versus uncontrolled dying. Donation after circulatory determination of death is termed "uncontrolled" when death is due to unexpected or sudden circulatory-respiratory arrest.

Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

Donation after circulatory determination of death (DCDD) is termed "uncontrolled" when death is due to unexpected or sudden circulatory-respiratory arrest. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations.

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the Nation. Improving Health.

Characteristics of controlled and uncontrolled DCDD might include:

Controlled DCDD (Maastricht III):
- On ventilator
- DNR (no attempted resuscitation)
- Located in the intensive care unit
- Timing of death is controlled
- In situ organ preservation unnecessary
- Family consent can be readily obtained before interventions.

Uncontrolled DCDD (Maastricht I, II, IV):
- Not on ventilator
- Resuscitation normally is attempted
- Located in field, emergency department, hospital
- Timing of death is uncontrolled
- In situ organ preservation (cooling) is necessary
- Family consent is difficult to obtain before preservation interventions need to be started

Areas of consideration relevant to uncontrolled DCDD include, what should the professional standards be—professional considerations. What criteria are necessary to respect the dead donor rule—ethical considerations. What criteria are necessary to preserve the public trust that resuscitation is the first priority—public considerations. What legal criteria are compatible with organ donation—legal considerations.

Dr. Goldfrank presented the standard criteria for terminating advanced cardiac life-support efforts (ACLS). ACLS may end if the patient is unresponsive after basic CPR is provided; ventricular fibrillation is eliminated; advanced airways device is placed; oxygenation/ventilation is achieved; intervention has been sustained for more than 10 minutes; and rhythm appropriate drugs have been administered.

Dr. Goldfrank concluded by outlining the various areas of consideration relevant to uncontrolled DCDD. At the end of the day, what should the professional standards be—professional considerations. What criteria are necessary to respect the dead donor rule—ethical considerations. What criteria are necessary to preserve the public trust that resuscitation is the first priority—public considerations. What legal criteria are compatible with organ donation—legal considerations. And, finally, it is important to determine what research is necessary to advance the field.

POTENTIAL IMPACT

Potential for Increased Organ Donation

John Gallagher discussed the potential for increased donations following uncontrolled DCDD and introduced the experiences of a hospital in Madrid, Spain that has performed uncontrolled DCDD for more than 15 years. Spanish law allows institution of organ preservation until the next-of-kin either consents to or refuses organ removal. As soon as the patient is pronounced, and following the hands-off period, the transplant team begins cannulation and cooling, obtains blood samples, and assumes care under previously established conditions (e.g., presumed consent, prior community agreement, or enabling legislation). There must be less than 120 minutes of total warm ischemia time (i.e., from the moment of collapse until cannulation and cooling begins). The medical examiner is contacted, depending on local legal requirements. The family is contacted and notified of the death per the institutional protocol; a trained member of the transplant team makes the donation request from the family within four hours. This protocol has yielded a 93 percent consent rate for kidney donation (see Sanchez-Fructuoso et al., 2006, Annals of Internal Medicine 145:157-164).

To obtain an estimate of the number of uncontrolled DCDD donors, Dr. Gallagher used conservative criteria modified from the Madrid experience (see IOM, 2006, p. 139) and applied this information to data obtained from the New York

City PHASE study (Pre-Hospital Arrest Survival Evaluation). The PHASE study was conducted in New York City in the early to mid-1990s to assess survival following out-of-hospital cardiac arrest. Trained paramedic research associates performed immediate post-arrest interviews with out-of-hospital care providers using a validated, standardized data collection instrument. Dr. Gallagher specifically noted that cardiac arrests associated with trauma were excluded from this dataset. Thus, the number of potential uncontrolled DCDDs following out-of-hospital cardiac arrests could be significantly higher if eligible trauma patients were added to this cohort.

The PHASE study gathered data on 3,243 consecutive out-of-hospital cardiac arrests during a six-month period in New York City. Of these, 2,329 met entry criteria as primary cardiac events. In examining the PHASE data, it was determined that 178 of the non-survivors (about 7.6%, 99% confidence interval 6.6–8.7%) met the Modified Madrid Criteria (excluding trauma cases). These criteria included age under 50 years, receipt of CPR within 15 minutes of witnessed collapse, and pronouncement of death within 60 minutes of onset of cardiac arrest. An application of the lower limit of the confidence interval (6.6%) to the American Heart Association estimate of 335,000 out-of-hospital cardiac arrests occurring annually in the United States, suggests the availability of approximately 22,000 potential uncontrolled DCDD donors in the United States each year. These calculations use conservative approximations and are meant to provide a preliminary working estimate of the number of additional potential kidney donors available from this untapped pool of out-of-hospital cardiac arrests.

It is estimated that each year in the United States there are 22,000 potential uncontrolled DCDD organ donors.

Dr. Gallagher concluded by noting that outcomes from fifteen years of experience in Madrid indicate that despite the expected delayed graft function seen in most DCDD kidneys, one- and five-year graft survival rates compare favorably with graft survival of kidneys transplanted following neurologic determination of death. Furthermore, one- and five-year graft survival rates for DCDD in the Madrid experience are actually better than for those of DNDD donors over age 60.

Cost-Benefit Analysis – Issues to Consider

David Howard discussed the limited cost-benefit data on kidney transplantation and the lack of data specific to uncontrolled DCDD. One study compared costs between high- and low-risk recipients by donor type: extended criteria donor (ECD) and non-ECD. Costs for patients who received ECD kidneys were higher than for those who received non-ECD kidneys, regardless of the risk status of the recipient. Transplantation was found to be cost-effective for a five-year time horizon in three of the four categories of recipient/donor and for all four categories over 20 years.

Studies that compare the costs of transplantation to the costs of remaining on dialysis are of particular interest. Dr. Howard noted that while ongoing costs for patients on dialysis are higher than costs for patients on maintenance immunosuppressive therapy, mortality rates for patients on dialysis are also higher, so it is not immediately clear that transplantation is cost-saving relative to transplantation in the long-run. Several recent studies have found that transplantation using kidneys from ECDs and transplantation with kidneys from living donors is cost-saving over a 20-year period when compared with the long run costs of remaining on dialysis from the perspective of the Medicare program. A more recent study of the long-run costs incurred by patients with private insurance found that kidney transplantation is cost-increasing: ten-year costs for all transplant patients are $163,474 compared to $146,538 for dialysis recipients. However, kidney transplantation is cost-saving for living donor transplant recipients and patients who are on dialysis largely because patients are transplanted earlier, while healthier, and the donated organs have fewer complications and are frequently a better match.

The cost-benefit analysis of DCDD could be examined by comparing costs for

those who stay on the waiting list and DCDD kidney transplantation; staying on waiting list and non-DCDD kidney transplantation; and so on. A new study is examining UNOS data for one-, three- and five-year outcomes for DCDD and non-DCDD kidney recipients.

Dr. Howard also noted that it is important to consider how this type of donor recovery would affect the OPOs. Economies of scale will be important in terms of instituting programs; the more they can be ramped up quickly, the lower costs will be for the OPOs. It might be necessary to think about providing extra payments and/or incentives to encourage centers to accept DCDD organs.

INSIGHTS FROM THE WASHINGTON, DC EXPERIENCE: CASE STUDY AND LESSONS LEARNED

The Rapid Organ Recovery Program focused on trauma deaths in patients with non–survivable brain injury who did not meet neurologic death criteria. For these patients, uncontrolled DCDD provided the organ donation option for the surviving family.

Jimmy Light discussed the Rapid Organ Recovery Program conducted in the late 1990s in Washington, D.C. This program is the most extensive uncontrolled DCDD program conducted in the United States to date. The Rapid Organ Recovery Program focused on trauma deaths in patients with non–survivable brain injury who did not meet neurologic death criteria. For these patients, uncontrolled DCDD provided the organ donation option for the surviving family. (It was noted in passing that the IOM estimation of the potential pool of uncontrolled DCDD donors excluded trauma deaths, and thus was likely a significant underestimation of the actual number of potential donors).

Dr. Light described the system needs for implementing an uncontrolled DCDD process. The program's protocol and defined roles were developed to ensure that warm ischemia time was less than 45 minutes. Participating staff included family advocates who interfaced with the medical examiner, the homicide team, and the OPO. An on-site preservation team and equipment was used to conduct bedside cannulation and cooling to begin organ preservation in situ. After recovery, kidneys were biopsied and placed on machine preservation and, if the kidneys were satisfactory, then allocation was made based on UNOS (United Network for Organ Sharing) criteria to the most appropriate recipients. Average total ischemia time was about 23 hours, but in two cases was well over 30 hours. Ischemia time should be shorter with current technology.

When the Rapid Organ Recovery Program began, the donor family had to give consent to initiate preservation. However, this could be accomplished in only 10 percent of the potential donors within the 45-minute window. Most families could be contacted within 4 hours, and most of them authorized tissue donation. As a result of these data accumulated over a one year period, the D.C. City Council amended the Uniform Anatomical Gift Act (UAGA) to authorize hospitals to initiate organ preservation procedures in order to provide family members with the option of donation. The changes were as follows:

- In the event that the next-of-kin is not immediately available for consent to be requested, the hospital may use organ preservation and techniques to maintain the viability of the decedent's organs... in order to preserve the option to consider organ donation.
- Use all available methods to contact the next-of-kin for organ donation; if not reached in a reasonable time, discontinue in situ preservation.
- Individuals and hospitals are immune from liability.
- Decedent/family bears no costs.

Dr. Light noted that the Rapid Organ Recovery Program did not experience pushback from caregivers, probably because the process was implemented slowly

and concerns were addressed along the way until everyone was comfortable with it. A significant amount of time was devoted to discussions with the general public and media interactions, spearheaded by the director of the family advocates program.

External grant support provided initial funding for the family advocate system and the organ preservation laboratory and helped build institutional support. Dr. Light explained that the existence of funding encouraged the systems change. There would not have been a family advocate program without the external funding, and without the family advocates, there could not have been a Rapid Organ Recovery Program. The main point is that most health care institutions can not commit the start up funds and resources needed to institute this type of organ and tissue recovery system. Once the system is well entrenched, then recovery and utilization fees should sustain the program.

Dr. Light discussed the process for rapid organ recovery. To achieve optimal kidney preservation it is necessary to get the body to about 15 degrees Celsius as rapidly as possible. The group's research showed this was not possible with intravascular cooling alone (the technique used in Europe). The D.C. group used modified laproscopy tubes to initiate intraperitoneal cooling and a heat exchanger to supercool the solutions, along with the traditional intra-vascular cooling with the triple lumen, double balloon catheter. These combined techniques reduced the core temperature to about 15 degrees within about 30 minutes. The mean warm ischemia time (from cardiac arrest to initiating flush) was 28 minutes with a range of 7 to 60 minutes. Mean in situ preservation time (e.g., kidneys preserved in the donor) was 2 hours and 24 minutes, with a range of 1 to 6.5 hours.

The group discussed what Dr. Light had described as the keystone to making organs available: rapid cooling and immediate surgical capacity. In D.C., the team was always on-site, surgical carts were located in all of the intensive care units, and the preservation fluid was always kept cool. The median time of 28 minutes from death to cooling the organs is not possible without trained in-house personnel. Dr. Light's view is that uncontrolled DCDD is really only feasible in significantly sized trauma units; otherwise, there are too few cases to keep staff at adequate levels and to maintain expertise, assuming that current hypothermic technology is utilized.

The transplanted kidneys had immediate function in nine instances; delayed function in 20; and non-function in two where preservation times exceeded 30 hours and the recipients were higher immune risk. Patient survival and graft survival were equivalent for about 4 years but not as good as expected in later years, perhaps due to ischemic damage. The number of patients was small, however, and their results should not drive the discussion. Selecting appropriate recipients is an important part of getting good results. Recipient selection should be based on physician and patient willingness to accept a DCDD organ with its attendant risks, noted in advance in the patient's file to speed organ allocation (much as it is done for ECD recipients). High-immune risk or technically difficult recipients should be avoided.

The group discussed whether a controlled DCDD program must be in place in order to start an uncontrolled DCDD program. Dr. Light noted that when they were conducting the uncontrolled DCDD program, the OPO did not have a controlled DCDD program, which made implementing the uncontrolled program more difficult. Dr. Light felt that controlled DCDD should be implemented first, and then expanded to include the uncontrolled DCDD. However, another participant stated that the ethical issues and the support needs vary between the two processes.

The family advocate program was essential to the Rapid Organ Recovery Program. A significant amount of time was devoted to discussions with the general public and media interactions, spearheaded by the director of the family advocates program.

ETHICAL ISSUES

Jim DuBois presented the different ethical issues relevant to DCDD under controlled versus uncontrolled situations. In the United States, controlled DCDD raises issues regarding the withdrawal of ventilation, determination of the length of wait-time following circulatory arrest, and the use of heparin. These issues are non-existent with uncontrolled DCDD, as the donor is not on a ventilator, and medical professionals attempt to resuscitate them. It is the timing of the death, and not the process, that is uncontrolled. Dr. DuBois noted that in the United States, the issue of consent is key. On the one hand, there is a strong tradition of not performing medical procedures on the living without their consent, and a strong tradition of allowing families to determine the treatment of the deceased. On the other hand, most people in the nation favor donation; most Americans who sign a donor card assume that they will be donors, but most will not currently have the chance (only 6 of 1,000 deceased individuals have the chance to actually donate). Preservation leaves open the opportunity to exercise autonomy. Increased donation, moreover, saves lives.

Most people in the nation favor organ donation; most Americans who sign a donor card assume that they will be donors, but most will not currently have the chance (only 6 of 1,000 deceased individuals have the chance to actually donate).

Dr. DuBois raised the question, should we make the consent issue moot? In the absence of statutes explicitly permitting preservation, it could be best to start with those individuals who have a donor card and/or have joined registries. First person consent is generally now honored and registries have improved access to consent information. Other consent issues that should be considered include whether we should create opportunities to opt out. There are no good ways to do this right now. When someone does not sign an organ donor card, they are not explicitly saying they do not want to be a donor and their family would be contacted in an uncontrolled situation. People could be given an option to choose: "I want to be a donor," "please talk to my family," or "I don't want to be a donor." Then, only in the latter situation would the organs not be preserved.

The criteria for uncontrolled DCDD must be trusted by the public at least as much as is the case in DNDD—or the public itself may insist on the implementation of special consent for uncontrolled donation. People need to know they will really be dead before procurement occurs. Issues that complicate uncontrolled donation include trust and resuscitation. People fear that their doctors will not try as hard as possible to save their lives if they are organ donors. Dr. DuBois stated that education is needed to correct this belief. We also need to guarantee gold standards for resuscitation efforts. Europe uses 30 minutes of attempted resuscitation and 10 minutes of a hands-off period. The IOM in the 2006 report did not insist on a hands-off period, but there may be a need for one, even if it is short and primarily symbolic. Health care workers' views are likely to be more supportive if there was a short transition period between patient and donor status. It is also critically important that the individual who discontinues resuscitation is not affiliated with any donor program. Without public support, organ donation cannot occur.

Dr. DuBois further noted that organ quality must be acceptable. In time, the quality is likely to improve, although research and quality assurance are both necessary. But, if the quality is found to be unequal, extended criteria rules should apply. Special consent would be needed from the potential recipients and special allocation rules implemented.

Uncontrolled DCDD and living donation each have pros and cons as outlined in Dr. DuBois' presentation. Living donation has lower costs, yields better graft survival and better quality of life, and can greatly expand the pool of donors. The negative issues regarding living donation are that a few healthy donors are going to die, someone is going to be hurt, and there are concerns about coercion. These negative issues led the 2006 IOM committee to explore DCDD more intently.

The group discussed issues of diversity as they affect uncontrolled DCDD, particularly that mistrust of the medical system is exacerbated by disparities and is a factor in organ donation. Barriers to health care services exist, particularly in large cities that have health care disparities, and this reality may drive the success of the program. Dr. DuBois noted that the 2006 IOM committee felt that increasing the pool of organs will help to diminish disparities and is one way to improve the situation. Another participant noted that there is a danger that people will be confused by the problems that have been publicized in whole body donation.

LEGAL ISSUES

Richard Bonnie discussed the relevant legal issues, with particular attention to the core issue of preservation without explicit consent. He began by assuming that it is ethically permissible (at the very least), and may be ethically required, to preserve organs for possible donation while seeking explicit consent, as it preserves options and autonomy. The question, Mr. Bonnie noted, is whether "the law" currently impedes this ethically permissible activity, either because it clearly requires explicit consent before preservation can be undertaken or because legal uncertainty about the issue deters doctors and hospitals from undertaking preservation in the absence of explicit consent.

One point is clear, Mr. Bonnie said: A recorded desire by the deceased to be a donor provides sufficient authority to preserve organs for this purpose, even if the practice is also to seek family consent. The uncertainty arises when the deceased person's wishes are unknown, and family authorization is being sought. In some states and locales, such as Virginia, Washington D.C., and Illinois, statutes explicitly permit preservation activities prior to obtaining consent. Florida also has a "preservation pending consent" law. However, most states do not have such statutes, and whether the law permits preservation pending consent is admittedly uncertain.

The argument that preservation pending consent is not permissible proceeds as follows. The assumption is that as long as a person is alive, he or she has to give explicit consent, so that prerogative goes to the family members when that person dies, and they must give explicit consent. This assumption is an extension of the views about control over the body: that the baton of control passes to the family. So, one legal assumption could be that the law must explicitly say it is acceptable to conduct preservation without explicit consent. Mr. Bonnie contended, however, that this view reflects a misunderstanding of existing law.

The question, is whether "the law" currently impedes this ethically permissible activity, either because it clearly requires explicit consent before preservation can be undertaken or because legal uncertainty about the issue deters doctors and hospitals from undertaking preservation in the absence of explicit consent.

Two lines of arguments were outlined by Mr. Bonnie in support of his view that current law authorizes preservation pending family consent. The first is that the authority is implicitly conferred by the UAGA. The Act's purpose is to facilitate organ donation; it includes many provisions for doing this, such as the requirement that a reasonable search for donation documents be made. Normally (e.g., in a controlled situation) there is time to conduct such a search and contact the family before the individual is deceased. There is implicit authority, then, to preserve the organs while the search for documentation and the family is being conducted. And, the immunity provision protects those who attempt in good faith to comply with spirit and letter of the UAGA. The Act does not preclude preservation. Moreover, organ preservation is arguably analogous to the common practice of maintaining a patient on mechanical ventilation following a neurological determination of death in order to enable a request for donation.

The second argument is that preservation pending consent does not violate family legal rights. Mr. Bonnie noted that there is an exaggerated understanding of families' legal rights in this area. The family's legal interest in the body of a deceased

person is neither an extension of the autonomy that the deceased person exercised while he or she was alive, nor a property interest belonging to the family. The families' right is the right to have possession of the body and make the final disposition of it. It is a very limited right that can be overridden by the state's interest in, for example, conducting an autopsy. Organ procurement organizations are sometimes told by families that consent for donation is denied because the family has concerns about mutilation. However, the incisions required for organ preservation do not amount to mutilation in a legal sense, Mr. Bonnie observed. This may be less of a legal issue and more of an educational issue around what happens to the body after death.

The group discussion focused in part on the possibilities of regulation rather than legislation. Discussion also revolved around ensuring that correct terms are used. Several participants noted that, in terms of public awareness, people need to be clear that we are talking about cardiac arrests, not heart attacks.

One question that needs to be resolved is whether community education needs to focus on uncontrolled DCDD or whether focus groups and town hall meetings should focus on the trust issues that are connected with organ donation in general.

OPPORTUNITIES AND BARRIERS TO UNCONTROLLED DCDD: NATIONAL AND METROPOLITAN PERSPECTIVES

The group met in breakout sessions to consider specific issues and barriers to the implementation of uncontrolled DCDD efforts in Chicago, New York City, and Washington, D.C. A fourth breakout session focused on national policy issues.

Chicago

Members of this breakout session included: Jim DuBois, Michael Harmon, Bernard Heilicser, Stephen Jensik, Mark Kuczewski, and Martin Mozes. Notes from the breakout session highlighted the following areas of the group's discussion:

- Obstacles: Identifying space to be used for these procedures is an unresolved issue, as is preservation. The group felt that re-routing ambulances to just a few organ retrieval centers would be riskier for EMS staff, who would need to travel further through the city than usual. The UNOS allocation criteria were also seen as a barrier and as a disincentive for the OPO. It would be a benefit and an incentive if the OPO could get an exemption for uncontrolled DCDD.
- Staffing: The group saw a need for a dedicated staff person to be ready to do the preservation, but felt that there are not enough emergency department staff to conduct preservation. Paraprofessional staff could be used. The group felt that uncontrolled DCDD would result in few changes for emergency medical services (EMS), as pronouncement should occur in the hospital. The only changes for EMS personnel would be that they would not extubate; the donor should remain intubated to aid preservation, and death should be pronounced in the emergency room rather than in the field.
- Professional support: The Chicago group emphasized the importance of involving coroners and medical examiners. National criteria/standards would be helpful in encouraging hospitals to become engaged.
- Community public relations and education: The group felt that these efforts should occur at the hospital-based level, with the local community. One question that needs to be resolved is whether this education needs to focus on uncontrolled DCDD or whether focus groups and town hall meetings should focus on the trust issues that are connected with organ donation in general.
- Demonstration projects: The group identified a cluster of hospitals around Cook County Hospital where this process could be started, with effort. If there cannot be

one person at each hospital, then one person could cover the three sites and triage will be necessary. The suggestion was to begin with patients who were on the organ registry.

- Terminology: The term "emergency room organ donation" was suggested by one member of the group, though the group could not agree on a name. Group members did not like the use of abbreviations and felt that avoiding abbreviations will help to educate the public about what this involves and where it happens. One audience participant suggested that no special name is needed, that we should always just refer to "organ donation" and protocols can specify details for specific situations.

New York City

Members of this breakout session included: Richard Bonnie, Dolph Chianchiano, Joseph Cooke, Nancy Dubler, Van Dunn, John Gallagher, Lewis Goldfrank, Eric Grossman, Brad Kaufman, Ginny McBride, Tia Powell. The New York group's discussion generated a "to do" list that includes legal counsel letters, a demonstration project letter, pre-hospital demonstration EMS involvement, and seeking a grant from HRSA. Specific discussion points included:

- Logistics: The group suggested using existing trauma centers and leveraging underutilized trauma teams. The group emphasized that it will be necessary to obtain the buy-in from transplant surgeons, and to work with EMS to modify post-resuscitation and transport protocols.
- Finance: Financial issues discussed by the group included the costs of personnel, family advocates, operating room equipment, and hospital time. It was noted that an upcoming Health Resources and Services Administration (HRSA) grant might help cover some of these costs.
- Legislation: The New York group wants to seek an opinion letter from the general counsel of the Health and Hospital Corporation so they can move ahead with a demonstration project without necessitating specific legislation.
- Research: The group emphasized the importance of integrating uncontrolled DCDD into current research efforts to improve resuscitation.
- Communications and public involvement: The group focused much of its discussion on how to engage the community and develop trust in uncontrolled DCDD. It is important to gain buy-in from those entities providing medical care to the community. The New York group intends to reach out to key individuals and organizations and noted that community planning boards are good routes for education and information. It will also be important to work with leaders and change agents in the community, such as religious groups and African American women.
- Messaging: Professional advice and analysis will be critical to developing an effective message. The group felt that a public campaign is needed to emphasize that the goal is to save lives with this form of organ donation. It will be important to demonstrate, across the spectrum of care, that the focus is on preventing disease and saving lives, and that only when resuscitation fails does donation become the priority.
- Stakeholder analysis: The group felt that stakeholders include patients, families, recipients, transplant surgeons, trauma surgeons who will retrieve organs, emergency physicians, EMS staff, and hospital staff.

It is is important to gain buy-in from those entities providing medical care to the community. It will also be important to work with leaders and change agents in the community, such as religious groups and African American women.

Washington, D.C.

Members of this breakout session included: Leigh Boghossian, Clive Callender, David Ciesla, Carlos Fernandez-Bueno, Nader Habashi, Jimmy Light, Kevin Myer, William Ritchie, Heather Shank-Givens, Dennis Wagner, and Michael Williams.

Notes from the breakout session highlighted the following areas of the group's discussion:

- Infrastructure, challenges and barriers: The group felt that Washington, D.C. is at a high state of readiness with the resources, desire and experience to conduct uncontrolled DCDD. Use of the regional trauma center infrastructure and routing pre-hospital triage through the trauma centers rather than the emergency departments was discussed. Issues regarding initiation of preservation and operating room availability were deemed to be manageable. Community input is strong and the OPO is now interested in working on this issue. Implementing a new uncontrolled DCDD initiative will require some re-engineering and new resources, but the group felt that it is possible.
- Professional support: There is a need for trauma surgeons to initiate preservation activities as an extension of end of life care after death has been declared. This simple change preserves the donation option for families, and buys time to assemble organ preservation and recovery teams. Staff will need to be re-educated, but the group felt that it could be done with the structure and protocol used before, with the assistance of family advocates, and with the advent of better preservation solutions and devices. Professional support is likely to be enhanced by the increases in donations.
- Impact: The potential impact on emergency departments is unknown; it will be necessary to look at how EMS triages and to create systems that triage likely patients and route them to trauma centers. The group emphasized the importance of being clear about the space needs that will be required, and taking into consideration any resulting strain on the system.
- Terminology: The group suggested using a process similar to the last time that Washington, D.C. conducted this process and gather community input on the program's/process' name. Something that references organ donation would be most clear to the public. It is probably worth the effort to generate a program name that is unique and clear. The group also thought that one term for uncontrolled DCDD should be used across the United States rather than varying by location and that the Organ Procurement and Transplantation Network (OPTN) should take on this task.

The group felt that Washington, D.C. is at a high state of readiness with the resources, desire and experience to conduct uncontrolled DCDD. Use of the regional trauma center infrastructure and routing pre-hospital triage through the trauma centers rather than the emergency departments was discussed.

National Policy Group

Members of this breakout session included: James Burdick, Jim Childress, Frank Delmonico, Richard Durbin, David Howard, Howard Nathan, Alan Rubenstein, Paul Schwab, and Jim Warren. Notes from the breakout session highlighted the following areas of the group's discussion:

- Stakeholders: There is a need to educate medical professionals on this issue. The group thought it might be useful for the Joint Commission to draft a focus paper on uncontrolled DCDD, like the one it created earlier on organ donation. Surgeons have concerns about outcomes and the cost of keeping the recipients in the hospital for a longer period of time. There is a new push to gather outcome data about organs that a center rejected, and provide this back to the center as a way to help staff assess their decision-making when rejecting an organ. Recipient selection is an issue: it is anticipated that organs from uncontrolled DCDD donors will not go to high-risk patients; recipient selection will help address issues of cost.
- Change in practice: With controlled DCDD, there was already an end-of-life care system in place, and the mindset of providers was established. Uncontrolled DCDD requires a change in practice. The practice has not been set yet and in some cases a staff person is being asked to functionally change what they do in a situation.
- Risk management: The group felt that a large issue for hospitals will be risk management and cost-benefits. It may be cost-beneficial in practical and medical

terms, but hospitals may still worry about potential lawsuits.

- Pilot studies: The group considered the advantages of implementing a pilot study on uncontrolled DCDD in a state or area with both first person consent and a donor registry. People think they are going to be a donor when they get their card, and most would be astonished to learn that it is not necessarily going to happen—depending on how they die.

NEXT STEPS IN IMPLEMENTING UNCONTROLLED DCDD PROGRAMS

The group reconvened to hear the reports from the breakout sessions and to focus on next steps for uncontrolled DCDD in the United States. Dr. DuBois noted that although some obstacles had been noted in the groups' discussions, there are many opportunities and much interest in pursuing the implementation of pilot programs on uncontrolled DCDD. The group discussed whether a national consensus conference or a national taskforce on uncontrolled DCDD is needed, but it was agreed that the present meeting and the 2006 IOM report provided sufficient basis for local efforts, and that local buy-in is perhaps more urgently needed. However, it is important for key national organizations to demonstrate their support (e.g., American Society of Transplant Surgeons [ASTS], OPTN) for uncontrolled DCDD. The group also discussed whether uncontrolled DCDD should be promoted by the HRSA Breakthrough Collaborative. However, it was observed that the Collaborative's purpose is to promote data-supported best practices, and uncontrolled DCDD is still in its infancy and requires demonstration projects and data.

HRSA funding options were discussed that include clinical intervention grants focused on examining technical factors to increase donation. This grant program could be an appropriate mechanism to fund demonstration projects. The group suggested beginning with programs in states that have organ donor registries. Success in locating individual hospitals that are enthusiastic about involvement will be another critical element.

Next steps could focus on implementing pilot programs on uncontrolled DCDD in states that have organ donor registries. Success in locating individual hospitals that are enthusiastic about involvement will be another critical element.

The group agreed that there is a better foundation for uncontrolled DCDD efforts than there was a decade ago. Ongoing discussions and efforts by participants of this meeting and others in their cities and organizations will be essential in advancing the implementation of uncontrolled DCDD programs and increasing the number of organ donors.

MEETING PARTICIPANTS

Leigh J. Boghossian
Emory University

Richard J. Bonnie
University of Virginia

Jim Burdick
Health Resources and Services Administration

Clive O. Callender
Howard University

Dolph Chianchiano
National Kidney Foundation

James F. Childress
University of Virginia

David J Ciesla
Washington Hospital Center

Joseph T. Cooke
New York-Presbyterian Hospital

Francis L. Delmonico
New England Organ Bank

Joy DeMas
Health Resources and Services Administration

Nancy N. Dubler
Albert Einstein College of Medicine

James M. DuBois
Saint Louis University

Van H. Dunn
New York City Health & Hospitals Corporation

Richard Durbin
Health Resources and Services Administration

Carlos Fernandez-Bueno
Washington Regional Transplant Consortium

E. John Gallagher
Albert Einstein College of Medicine

Lewis R. Goldfrank
NYU School of Medicine
Bellevue Hospital Center

Eric B. Grossman
New York Organ Donor Network

Nader M. Habashi
University of Maryland Shock Trauma Center

Michael Harmon
Gift of Hope Organ & Tissue Donor Network

Bernard Heilicser
Ingalls Memorial Hospital

Nora M. Hennessy
Institute of Medicine

David H. Howard
Emory University

Stephen C. Jensik
Rush-Presbyterian-St Luke's Medical Center

Brad Kaufman
New York City Fire Department

Mark G. Kuczewski
Loyola University Chicago

Jimmy A. Light
Washington Hospital Center

Catharyn T. Liverman
Institute of Medicine

Ginny McBride
Health Resources and Services Administration

Martin F. Mozes
Gift of Hope Organ & Tissue Donor Network

Kevin A. Myer
LifeNet

Howard M. Nathan
Gift of Life Donor Program

Andrew Pope
Institute of Medicine

Tia Powell
New York State Task Force on Life & the Law

William Ritchie
Washington Hospital Center (ret.)

Alan Rubenstein
President's Council on Bioethics

Paul M. Schwab
Association of Organ Procurement Organizations

Heather Shank-Givens
Washington Regional Transplant Consortium

Vilija Teel
Institute of Medicine

Dennis Wagner
Health Resources and Services Administration

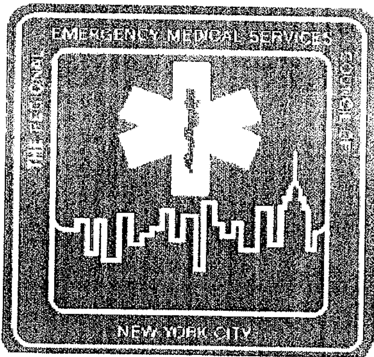
Jim Warren
Transplant News

Michael D. Williams
Washington, D.C. Fire and EMS Department

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

The nation turns to the National Academies—National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council—for independent, objective advice on issues that affect people's lives worldwide.

THE REGIONAL EMERGENCY MEDICAL SERVICES COUNCIL OF NEW YORK CITY, INC.



REGIONAL EMERGENCY MEDICAL SERVICES COUNCIL OF NEW YORK CITY			
Advisory No.	2008-01		
Title:	Clarification of Determination of Death		
Issue Date:	January 1, 2008		
Effective Date:	Immediate		
Re-Issued:	N/A		
Supercedes:	N/A	Page:	1 of 27

The Regional Emergency Medical Services Council (REMSCO) of New York City has researched and clarified how EMS Providers can determine death in the prehospital environment. This advisory has been approved by the Regional Emergency Medical Services Council for use in the NYC region.

Owners/operators of Ambulance and ALS First Response Services providing prehospital medical treatment within the five boroughs of the City of New York are responsible to provide copies of this Operational Advisory to personnel and Service Medical Director.

Jeffrey Horwitz, DO

Chair, Regional Emergency Medical Services Council of New York City

THE REGIONAL EMERGENCY MEDICAL SERVICES COUNCIL OF NEW YORK CITY, INC.

Ambulance Operations /Systems Committee

Determination of Death by Prehospital Providers

The Regional EMS Council of NYC, Ambulance Operations / Systems Committee, formed a Technical Advisory Group (TAG) to develop an information guideline – not a policy or standard – to help EMS Agencies orient their personnel regarding Determination of Death by Prehospital Providers.

Below is a listing of frequently asked questions that can assist EMS Agencies in the development of policies and procedures regarding the determination of death by prehospital providers. EMS Agencies are encouraged to orient their personnel with regards to determination of death in the field.

INITIATION OF RESUSCITATIVE MEASURES AND THE PRESUMPTIVE DIAGNOSIS OF DEATH

Types of Death & Pronouncement

There are two types of death: natural and unnatural. Natural is defined by an Office of the Medical Examiner's memorandum dated April 12, 1990 (*Attachment 1*). The memorandum states, "death occurring at home, attended by a physician, does not fall under the jurisdiction of the medical examiner. A natural death is a death caused entirely by disease."

Unnatural deaths include, but are not limited to: criminal violence, all accidents (i.e., motor vehicle, industrial, home, public place, etc.), all suicides, sudden death of a person in apparent good health, etc.

1. **Who can pronounce a death?**

   Only a physician may pronounce a patient's death.

2. **Who may sign the Death Certificate?**

   The death certificate may be signed by the attending physician who has been providing medical care to the patient, has treated the patient for the disease causing death, and has examined the patient at appropriate intervals relative to the patient's disease and condition.[1]

Initiation of Resuscitative Measures

1. **When should Cardiopulmonary Resuscitation (CPR) be initiated by the EMT/Paramedic?**

   The Regional Emergency Medical Advisory Committee (REMAC) of New York City, Prehospital Transport and Treatment Protocols, General Operating Procedures, page A.8 (***Attachment 2***), states CPR should be initiated on all patients who are not breathing (apneic) and pulseless, unless one of the following conditions exists:

   - Extreme dependent lividity; **or**
   - Rigor mortis; **or**
   - Tissue decomposition; **or**
   - Obvious mortal injury; **or**
   - A valid Do Not Resuscitate (DNR) order is present.

[1] "Natural Deaths at Home," *Charles H. Hirsch, M.D. OCME Memorandum*, April 12, 1990.

2. **When should Cardiopulmonary Resuscitation (CPR) be stopped by the EMT/Paramedic?**

   The Regional Emergency Medical Advisory Committee (REMAC) of New York City. Prehospital Transport and Treatment Protocols, General Operating Procedures, page A 8 states CPR should be continued until one of the following occurs:

   - Spontaneous circulation has been restored; **or**
   - Resuscitative efforts have been transferred to providers of equal or higher level of training; **or**
   - A qualified, licensed physician assumes responsibility for the outcome of the patient; **or**
   - The crew is exhausted to the point of not being able to continue resuscitative efforts.

NOTIFICATION OF PRESUMPTIVE DIAGNOSIS OF DEATH

1. **Who must be notified?**

   In the case of death, there are many people that may need to be notified, such as the New York City Police Department (NYPD), private physicians, family members, funeral homes, etc. However, EMS personnel are not equipped to handle those tasks and should not be required to do so.

   In order to avoid unnecessary complications, it is recommended that NYPD attend each and every case of natural OR unnatural death, as NYPD is well equipped to make notifications, etc. EMTs/Paramedics must comply with the agency guidelines under which they operate, however, if certain conditions apply (*see 'Special Situations Concerning Presumptive Diagnosis of Death', page 5*) it may not be necessary to contact NYPD

2. **Under what circumstances must NYPD and the Office of the Chief Medical Examiner be notified?**

   EMS providers must call NYPD if there is any suspicion of foul play or if they question the validity of a supposed natural death.

   In the event of a crime scene, NYPD must be notified and asked to respond. EMS Personnel are not to handle crime scenes alone.

   a) Under what special circumstances are notifications made to agencies other than NYPD? This includes other law enforcement agencies, family members, press, etc

      EMTs/Paramedics are not required to make any notifications, other than notifying NYPD (when required to do so). Once NYPD has arrived at the scene, the EMT/Paramedic has no further responsibilities. Each agency should have a written policy in place regarding any additional responsibilities (if any) it wishes its employees to assume.

3. **How is notification made?**

   When a notification is required, notification should be made to NYPD only. There should be no notifications made to any private physicians, family members, or others who are not on the scene.

   Volunteer Ambulance Agencies should be directed to contact their neighborhood NYPD precinct.

4. What information should pre-hospital providers give NYPD?

In agreement with the FDNY Operating Guide Procedure, "Cancellation of Ambulance Response to DOAs", June 15, 1999 (*Attachment 3*), the appropriate information for presumptive diagnosis of death incidents shall include:

- name, certification number and expiration date of the EMT determining death.
- name of the EMS Agency.
- patient's name. address. age and sex. and
- most obvious cause of death.

5. How long must the EMT/Paramedic remain on the scene?

Each Agency must have its own policy, however, if NYPD has been called, an EMS provider must remain on scene until a police officer is present.

6. To what agency or to whom can the body be released?

In agreement with the FDNY Operating Guide Procedure, "Removal of the Deceased from the Scene of an Assignment" (*Attachment 4*). March 24. 2005. the body cannot be removed from a scene without the presence of NYPD and a report made (by NYPD) to the Office of the Chief Medical Examiner. EMS providers should not move decomposing bodies; this is to be done by mortuary units. Remember, the Office of the Chief Medical Examiner is the primary agency responsible for the removal of the deceased from the scene of an assignment regardless of location.

7. When and where can a body be left (i.e., situations when bodies must be removed)?

The only circumstance in which EMS providers should ever be involved in transporting the deceased is in cases of obvious death where the dead body is in public view. In these cases, law enforcement is on-scene. therefore EMS providers should follow the instructions of NYPD on-scene.

To ensure chain of custody of forensic evidence, all removals should be made by the Office of the Chief Medical Examiner. However, there are special exceptions made for public safety personnel at the discretion of the incident commander.

SPECIAL SITUATIONS CONCERNING PRESUMPTIVE DIAGNOSIS OF DEATH

1. **How does an EMT/Paramedic handle the notification of Presumptive Diagnosis of Death for Home Hospice Patients?**

An EMT or Paramedic is not required to report a death at home or in a home hospice program to the police if all of the following conditions are satisfied:

- The EMT or Paramedic is told by a physician that:
  - the death was due to disease or medical condition capable of causing such death;
  - the physician or the physician's associate has been providing medical care to the decedent;
  - such physician or associate has treated the decedent for the disease or medical condition causing death;
  - such physician or associate has examined the decedent within the 31 days proceeding death;
  - such physician or associate is willing to sign a death certificate certifying that the death was caused by such disease or medical condition;
- The evidence at the scene is, in the reasonable opinion of the EMT or Paramedic, consistent with death due to such disease or medical condition; and
- The EMT or Paramedic sees no evidence of criminal violence, accident, suicide, or death in any suspicious or unusual manner.

If any of the forgoing are not satisfied, there is a risk that the EMT or Paramedic could be charged with a misdemeanor for failure to notify the police.

In addition, if the EMT or Paramedic becomes aware of any evidence that the death was caused by criminal violence, by accident, by suicide, suddenly when in apparent health, or in an suspicious or unusual manner, the EMT or Paramedic is required to report such death to the police—even if the decedent is in a home hospice care program for a chronic terminal illness. Also, if the attending physician or his associate refuse to certify death due to disease or medical condition, the police and the OCME need to be notified even if the family or hospice object.[2] (*Attachment 5*)

2. **How do we inform NYPD that non-municipal EMTs can make a presumptive diagnosis of death in the field?**

A copy of this information guideline, in addition to a letter will be sent to the NYPD representative to the Regional EMS Council and to the NYPD Commissioner by the Regional EMS Council.

[2] "Reporting Deaths," Kinney Jr., *Stephen H. and Arlene Stevens. Thelen Reid Brown Raysman & Steiner. LLP* *Memorandum*, August 1, 2007.

Attachment 1

DEPARTMENT OF HEALTH
OFFICE OF CHIEF MEDICAL EXAMINER
520 FIRST AVENUE, NEW YORK, N.Y. 10016
Telephone: 212-340-

CHARLES S. HIRSCH, M.D., Chief Medical Examiner

[illegible]

[illegible]

[illegible]: Natural Death [illegible]

DATE: April 12, 19[illegible]

A natural death occurring at home, attended by a physician, does not fall under the jurisdiction of the medical examiner. A natural death is a death caused entirely by dis[illegible]

A person attended by [illegible] period of time may be enlarged in a particular case by the approval of the Chief Medical Examiner or a Deputy Chief Medical Examiner.

If the attending physician is available and willing to sign the death certificate, the family or friends in attendance may then call the funeral director of their choice. The attending physician does not have to see the body in order to sign the death certificate. If the attending physician is not available, a physician associated with the attending physician may sign the death certificate as long as he or she examines the body prior to signing the death certificate.

We want to avoid unnecessary [illegible] death occurs at home [illegible] where the decedent has been [illegible] terminal illness [illegible] situations, the patient may have been attended in the terminal stages of disease by friends, members of the family, health care or hospice workers, or home health attendants. If a person who has been attending a decedent under these circumstances contacts the OCME, they should be instructed as follows: (1) to call the attending physician (or a physici[illegible]

[illegible] then the police should be called, who then will respond to the scene and notify the OCME. The OCME will then respond and certify the death.

Attending physicians may also continue to sign the death certificates of persons who die unexpectedly at home if they have been under prior medical treatment for a disease or condition capable of producing sudden death, such as a heart attack occuring in a patient with coronary artery disease or hypertension. Under any circumstance, if there is any question about whether the person is dead or alive, the family or friends in attendance must call for emergency [illegible]

[illegible] certificate from the attending physician and file it with the New York City Bureau of Vital Statistics within forty-eight hours of death. If the funeral director has any reason to believe the death may have occurred from, or was contributed to, by other than natural causes, the funeral director shall not proceed further, and shall immediately notify the OCME.

This policy supersedes any other policy of the OCME on natural deaths occurring at home.

Attachment 2

NOTE: PATIENTS WHO BECOME CRITICAL OR UNSTABLE MUST BE TRANSPORTED TO THE NEAREST NEW YORK CITY 911 SYSTEM AMBULANCE DESTINATION EMERGENCY DEPARTMENT.

CARDIOPULMONARY RESUSCITATION

Basic Cardiac Life Support in adults, children, infants, and newborns should conform to the current guidelines set by the American Heart Association and the American Red Cross. The following guidelines apply to the initiation and termination of CPR:

CPR should be initiated on all patients who are not breathing (apneic) and pulseless unless one of the following conditions exists:

Extreme dependent lividity;

Rigor mortis;

Tissue decomposition;

Obvious mortal injury; or

A valid Do Not Resuscitate (DNR) order is present. (See Appendix C.)

NOTE: TERMINAL ILLNESS IS NOT A CONTRAINDICATION TO CPR.

CPR should also be initiated in newborns, infants, and children under 9 years of age with heart rates less than 60 (severe bradycardia) and signs of inadequate central (proximal) perfusion (decompensated shock).

NOTE: CPR IS NECESSARY IN NEWBORNS, INFANTS, AND CHILDREN UNDER 9 YEARS OF AGE WITH EXTREMELY SLOW HEART RATES AND POOR VITAL ORGAN PERFUSION TO ENSURE ADEQUATE CIRCULATION TO THE HEART, LUNGS, AND BRAIN.

CPR should be continued until one of the following occurs:

- Spontaneous circulation has been restored;
- Resuscitative efforts have been transferred to providers of equal or higher level of training;
- A qualified, licensed physician assumes responsibility for the outcome of the patient;
- The crew is exhausted to the point of not being able to continue resuscitative efforts.

AIRWAY MANAGEMENT

All patients require continuous monitoring of their airways to ensure airway patency. Wherever the term "Monitor Airway" is used throughout these protocols, the following elements shall be utilized:

Position of the patient's head

Need for airway adjuncts

Need for oropharyngeal suctioning

Attachment 3

EMSC OGP 109-04
DATE: JUNE 15, 1999

CANCELLATION OF AMBULANCE RESPONSE TO DOAS

1. PURPOSE

1.1 To establish a procedure for non-response, or cancellation, of an EMS Command response to incidents in which a presumptive diagnosis of death has been made by a NYS certified EMT, operating under the direct authority of a pre-hospital care provider agency, other than the FDNY EMS Command.

2. SCOPE

2.1 This procedure applies to all members of the FDNY EMS Command and the employees of voluntary hospitals who provide pre-hospital emergency medical care through the New York City 911 system.

3. POLICY

3.1 When a notification of a presumptive diagnosis of death has been made by a NYS certified EMT operating under the direct authority of a pre-hospital care provider agency, the FDNY shall:

3.1.1 Exercise the option to respond or not to respond to the incident.

3.1.2 Cancel the FDNY response, if previously initiated.

3.2 Notification of a presumptive diagnosis of death, and actions taken subsequent to the notification, shall be consistent with the criteria set forth in Operating Guide Procedure 106-09, *Initiation of Resuscitative Measures and the Presumptive Diagnosis of Death*.

3.3 Appropriate CAD information for presumptive diagnosis of death incidents shall include:

3.3.1 The name of the pronouncing EMT.

3.3.2 The EMT certification number and expiration date of the pronouncing EMT.

3.3.3 Name of the pre-hospital care provider for which the EMT provides service.

3.3.4 Patient's name, address, age, and sex.

3.3.5 Obvious death criteria.

3.3.6 Requests for cancellation of response by the EMS Command may be received either through the 911 system, or directly into Emergency Medical Dispatch (EMD), via the Mutual Aide Radio System (MARS) phone number. The MARS radio may not be utilized for notification.

4. PROCEDURE

4.1 Dispatcher shall:

4.1.1 When a notification of presumptive diagnosis of death is received, enter the following information related to the incident into the CAD system:

A. Call type: PDOD

B. Priority: Segment 9

C. Action Code: Not sent (N)

D. Text: To include, the appropriate CAD information for presumptive diagnosis of death incidents as described in Section 3.3.

NOTE: Use of Not Sent (N) action code will not generate a FDNY unit response. However, it will create documentation pertaining to the incident.

NOTE: If the information provided does not meet accepted criteria for a presumptive diagnosis of death, the call shall be processed for an appropriate FDNY response.

4.1.2 If a call is received, pursuant to this procedure, and a CAD assignment was previously created, the following actions shall be taken:

A. Verify the correct address of incident.

B. Change the call type of the existing CAD assignment as follows:

1. Call type: PDOD

2. Priority: Segment 9

3. Action Code: Change (C)

4. Text: To include the appropriate CAD information for presumptive diagnosis of death incidents as described in Section 3.3.

4.1.3 Cancel the original incident if it has not been dispatched. If a FDNY unit has already been assigned to the incident, notify the appropriate dispatcher to cancel the response to the incident.

5. RELATED PROCEDURES

5.1 OGP 106-09

BY ORDER OF THE CHIEF OF OPERATIONS

Attachment 4

EMSC OGP 106-10
March 24, 2005

REMOVAL OF THE DECEASED FROM THE SCENE OF AN ASSIGNMENT

1. PURPOSE

1.1 To establish a procedure for the removal of the deceased from the scene of an assignment.

2. SCOPE

2.1 This procedure applies to all members of the EMS Command and to Voluntary Hospital ambulance personnel who provide pre-hospital emergency medical care in the New York City 911 system.

3. DEFINITIONS

3.1 **Private Location** - shall be defined as those areas to which the public in general does not have access, such as a home, apartment, hotel room, or private office.

3.2 **Public Location** - shall be defined as those areas, which are open to the public or to public view.

3.3 **10-82M, (Location/Borough)** – Status signal indicating that a unit is transporting the deceased to the morgue.

4. POLICY

4.1 Office of the Chief Medical Examiner is the primary agency responsible for the removal of the deceased from the scene of an assignment regardless of location.

4.2 Removal of the deceased from any location may be ordered by an on-duty EMS Officer following authorization from the Office of the Chief Medical Examiner.

4.3 When authorized the removal of the deceased shall be performed by ambulance, with the exception of decomposed bodies, which shall only be removed by mortuary units.

4.4 At no time shall the deceased be removed without a NYPD Identification Tag (PD 317-091).

5. PROCEDURE

5.1 Prior to removal of the deceased from the scene of an assignment, members shall

5.1.1 Confirm with the Police that the death has been reported to the Office of the Chief Medical Examiner and a mortuary unit is not responding.

5.1.2 If available, record the M.E. Case Number on the Ambulance Call Report.

5.1.3 Confirm with the Police officer in charge that a search has been conducted and personal property removed.

5.1.4 Confirm that a NYPD Identification Tag (PD 317-091) has been affixed to the body. When confirmed the body shall be placed in a disposable body bag and delivered directly to the Medical Examiner's Morgue, in the borough of occurrence.

5.1.5 If a NYPD Identification Tag (PD 317-091) has not been affixed to the body, members shall:

A. Await the placement of a NYPD ID Tag prior to removing the body from the scene. When this is not possible, the body shall be left in the custody of a Police officer. Bodies shall not be removed from the scene without a NYPD ID Tag.

B If police officers are not present at the scene, members shall contact the dispatcher and request the response of the police. Members shall remain on the scene until the arrival of police officers, and the conclusion of a search for personal property.

C. At no time shall FDNY members sign the NYPD ID Tag. This document must be signed by the accompanying police officer upon arrival at the morgue.

5.4 Between 1600 and 0800 hours when an EMS unit in the borough of Staten Island, needs to transport a body to the Staten Island Medical Examiner's Office they shall:

5.4.1 Notify the dispatcher that they are removing a body, provide an estimated time of arrival (ETA) to the morgue and request the Medical Examiner's Office be contacted to ensure an attendant is present to accept the deceased.

5.4.2 If an attendant is not present to accept the body at the morgue, the unit shall:

A. Request the response of a Conditions Officer.

B. Request an ETA for a mortuary attendant.

5.4.3 When notified a unit is enroute to the Staten Island morgue, EMD shall contact the Medical Examiner, Office of Communications at (212) 447-2030 and provide the operator with an approximate ETA.

5.5 When the body of a deceased person is transported to the morgue, members shall secure a replacement disposable body bag from the morgue attendant

6. RELATED PROCEDURE

6.1 OGP 125-04, *Infection Control Program*

BY ORDER OF THE CHIEF OF EMS COMMAND

Attachment 5

M E M O R A N D U M

To: Nancy A. Benedetto
Executive Director, Administration
Regional Emergency Medical
Services Council of New York
City, Inc.

Date: August 1, 2007

From: Stephen H. Kinney Jr.
Arlene Stevens

Subject: Reporting Deaths

You have asked four questions concerning the duty of an Emergency Medical Technician (EMT) or a Paramedic to report certain deaths to the police. Your questions were as follows:

1. Is an EMT or Paramedic required to notify the police if a patient's death occurs at home or in a home hospice program in cases where the patient has been under long-term care for a chronic terminal illness, such as AIDS or cancer?

   a. Does the above also apply to sudden natural death resulting from a previous medical history such as a heart attack occurring from coronary artery disease or hypertension?

   b. What about a cardiac arrest with no known medical history?

2. Are there legal ramifications for not notifying the police when making a presumptive diagnosis of death if the patient died at home while under the care of a physician who has seen the patient within the past 31 days and is willing to sign a death certificate?

SUMMARY OF FINDINGS

Based upon a review of the authorities described in the Analysis below, an EMT or Paramedic is not required to report a death at home or in a home hospice program to the police if all of the following conditions are satisfied

1. The EMT or Paramedic is told by a physician that
    a. the death was due to disease or medical condition capable of causing such death;
    b. the physician or the physician's associate has been providing medical care to the decedent;
    c. such physician or associate has treated the decedent for the disease or medical condition causing death;
    d. such physician or associate has examined the decedent within the 31 days proceeding death;
    e. such physician or associate is willing to sign a death certificate certifying that the death was caused by such disease or medical condition;
2. The evidence at the scene is, in the reasonable opinion of the EMT or Paramedic, consistent with death due to such disease or medical condition and
3. The EMT or Paramedic sees no evidence of criminal violence, accident, suicide, or death in any suspicious or unusual manner.

If any of the forgoing are not satisfied, there is a risk that the EMT or Paramedic could be charged with a misdemeanor for failure to notify the police.

ANALYSIS

The New York City Administrative Code requires that certain deaths be reported to the police. Administrative code § 17-201 ("Section 17-201"), requires "any citizen who becomes aware of the death of any person, *occurring under the circumstances described in subdivision (f) of section five hundred and fifty-seven of the charter* to report such death" to the

office of the chief medical examiner and to a police officer. New York City Administrative Code §17-201 (2006) (emphasis added). Section 17-201 also provides that "any person who shall willfully neglect or refuse to report such death…shall be guilty of a misdemeanor." Id.

However, both the reporting requirements and the criminal penalty are limited to deaths that occur under the circumstances outlined in section 557(f) of the New York City Charter. The Charter gives jurisdiction to the Chief Medical Examiner in instances where death occurs "from criminal violence, by accident, by suicide, suddenly when in apparent health, when *unattended by a physician*, in a correctional facility or in any suspicious or unusual manner or where an application is made pursuant to law for a permit to cremate the body of a person." New York City Charter § 557(f) (2006) (emphasis added). Therefore, if the EMT or Paramedic becomes aware of any evidence that the death was caused by criminal violence, by accident, by suicide, suddenly when in apparent health, or in any suspicious or unusual manner, the EMT or Paramedic is required to report such death to the police - even if the decedent is in a home hospice care program for a chronic terminal illness. In addition, if the death occurs when the person is "unattended by a physician," the EMT or Paramedic must report the death to the police.

While the meaning of "attended by a physician" is unclear from the Administrative Code and the Charter, the Office of the Chief Medical Examiner ("OCME") has stepped in and provided clarification. According to a memorandum from Chief Medical Examiner Charles S. Hirsch entitled "Natural Deaths at Home," a person is "attended by a physician" when "a physician has been providing medical care to the patient, has treated the patient for the disease causing death, and has examined the patient at appropriate intervals relative to the patient's disease and condition." Memorandum from Chief Medical Examiner Charles S. Hirsch on Natural Deaths at Home (April 12, 1990). The Hirsch Memorandum

further elaborates by stating that, "[g]enerally, the physician should have seen the patient within thirty-one days of death, but that period of time may be enlarged in a particular case by the approval of the Chief Medical Examiner or Deputy Chief Medical Examiner." Id. According to the Hirsch Memorandum, the attending physician, or, if the attending physician is unavailable, his associate, is permitted to certify death in such cases. Id.

The OCME has also issued a directive which mirrors the Hirsch Memorandum. Directive 3-08, issued by the OCME and entitled "Natural Deaths At Home Not Requiring A Scene Visit," states that "[a] natural death occurring at home, attended by a physician, does not fall under the jurisdiction of the medical examiner ... this type of case is referred to as 'no case.'" Office of the Chief Medical Examiner, Policy on Natural Deaths at Home, Directive 3-08. The directive also provides that in such cases the attending physician, or, if the attending physician is unavailable, a physician associated with the attending physician, can sign the death certificate.

In the case of chronic terminal illness, both the Hirsch Memorandum and Directive 3-08 evidence the OCME's desire to avoid, if possible, causing the decedent's family and loved ones distress by asserting jurisdiction. The Hirsh Memorandum states "[w]e want to avoid unnecessarily taking jurisdiction when a death occurs at home or in a home hospice program in cases where the decedent has been under long-term care for a chronic terminal illness, such as AIDS or cancer." Memorandum from Chief Medical Examiner Charles S. Hirsch on Natural Deaths at Home (April 12, 1990). Directive 3-08 makes this aim even more clear, stating that, "[t]he investigator should have a sensitivity to the trauma caused by unnecessary exercise of medical examiner jurisdiction when a death occurs at home or in a home hospice program in cases where the decedent has been under long-term care for a chronic terminal illness

such as AIDS or cancer." Office of the Chief Medical Examiner. Policy on Natural Deaths at Home, Directive 3-08

The EMT or Paramedic arriving at the scene is in a difficult position. Usually, the EMT or Paramedic will have no prior knowledge of the decedent's medical condition. The family of the decedent may be upset, confused, emotional or, in the case of certain diseases such as AIDS, embarrassed. The attending physician may be difficult to reach. Given these difficulties, we have prepared the following checklist based upon the Administrative Code, the Charter, and the publications of the Office of the Chief Medical Examiner:

1. The EMT or Paramedic is told by a physician that

   a. the death was due to disease or medical condition capable of causing such death;

   b. the physician or the physician's associate has been providing medical care to the decedent;

   c. such physician or associate has treated the decedent for the disease or medical condition causing death;

   d. such physician or associate has examined the decedent within the 31 days proceeding death;

   e. such physician or associate is willing to sign a death certificate certifying that the death was caused by such disease or medical condition;

2. The evidence at the scene is, in the reasonable opinion of the EMT or Paramedic, consistent with death due to such disease or medical condition; and

3. The EMT or Paramedic sees no evidence of criminal violence, accident, suicide, or death in any suspicious or unusual manner.

If every item in the foregoing checklist is satisfied, the EMT or Paramedic need not notify the police. However, even if every item in this checklist is satisfied, there are risks to the EMT or Paramedic. The person claiming to be a physician might not be a physician. The

death might have been caused by poison, suffocation or conditions other than those for which the decedent had been treated. If the death later turns out to be reportable, the EMT or Paramedic could be questioned by the police or even charged, particularly if there were signs that the death was not natural or the EMT or Paramedic doesn't recall important details. The EMT or Paramedic should be alert for suspicious circumstances and, when in doubt, report the death to the police. The EMT or Paramedic may wish to keep written notes or other evidence that the checklist was satisfied.

The EMT or Paramedic in general is not required to notify the police or the OCME where the patient dies a natural death at home or in a home hospice program and the attending physician or his associate is willing to sign the death certificate. Thus, assuming no other facts, where a patient, who has been under long term care for a chronic terminal illness, dies at home or in a home hospice program as a result of such illness, the police do not need to be alerted if the patient was attended by a physician, as defined in the Hirsch Memorandum, and the attending physician or his associate is willing to certify death to such illness. A similar rule applies where a patient dies suddenly at home from a pre-diagnosed disease or medical condition capable of producing sudden death. For example, assuming no other facts, where the patient dies at home from a heart attack caused by hypertension or coronary artery disease, the police do not need to be contacted if the patient was attended by a physician, as defined in the Hirsch Memorandum, and the attending physician or his associate is willing to certify death to such causes.

However, if the attending physician or his associate refuse to certify death due to disease or medical condition, the police and the OCME need to be notified even if the family or hospice object. Unless otherwise permitted by the OCME, a physician should refuse to sign the death certificate if he or one of his associates has not treated the patient within 31 days preceding

death. See Office of the Chief Medical Examiner, Policy on Natural Deaths at Home, Directive 3-08 (stating that "[g]enerally, the physician signing the death certificate will have seen the patient within thirty-one days of death, but that period of time may be extended in a particular case on a case-by case basis with the approval of the Chief Medical Examiner or his designee"). Additionally, a physician should refuse to sign the death certificate if he believes that the death occurred from, or was contributed to by, other than natural causes. If the physician is unwilling to sign the death certificate for either reason, Section 17-201 would be triggered and both the police and the OCME would need to be notified. See Memorandum from Chief Medical Examiner Charles S. Hirsch on Natural Deaths at Home (April 12, 1990) (stating that in cases where the patient dies a natural death at home or in a home hospice program and was attended by a physician, the OCME should be contacted only when a death certificate cannot be obtained from the patient's attending physician or the attending physician's associate). Where an EMT or Paramedic is called to a home or hospice where the patient has died an apparent natural death, efforts should be made to contact the attending physician. If the attending physician or his associate cannot be located, or are unwilling to certify death due to disease or medical condition, the EMT or Paramedic should ensure that the police and the OCME are notified.

Likewise, there is a duty to report deaths where the patient dies suddenly when in apparent health. The Charter explicitly gives jurisdiction to the chief medical examiner when someone dies "suddenly when in apparent health." New York City Charter § 557(f)(2006). Since this situation falls under the circumstances of death outlined in the Charter, the reporting requirements of the Administrative Code are applicable. See, New York City Administrative Code §17-201 (2006). Thus, an EMT or Paramedic should ensure that both the police and the

OCME are notified where a patient with no known medical history dies suddenly, whether from cardiac arrest, stroke or otherwise.

CONCLUSION

Based on the assumptions described above, an EMT or Paramedic need not report to the police a death due to disease or medical condition occurring at home or in a home hospice program where the patient is attended by a physician, as defined in the Hirsch Memorandum, and that physician or his associate is able and willing to sign the death certificate. Because Section 17-201 is not applicable to deaths due to disease or medical condition when attended by a physician, there are no legal ramifications for not reporting such deaths to the police. However, an EMT or Paramedic should ensure that the police are notified where the patient dies suddenly when in apparent health, or where the attending physician or his associate is unavailable, unable or unwilling to sign the death certificate. In both instances, Section 17-201 requires the police and the OCME to be notified and provides a criminal penalty for failing to do so.

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

April 17, 2007

Dear Hospital Administrator

The Department, in conjunction with the New York State Task Force on Life & the Law, has recently reviewed the practice of Donation after Cardiac Death (DCD). DCD is the process by which patients donate their organs and tissue after being declared dead by cardiopulmonary criteria, as opposed to neurologic criteria.

In an effort to address the shortage of organs available for transplant, both the federal government and the Institute of Medicine have recommended the increased use of DCD. The United Network for Organ Sharing (UNOS) has endorsed the development of DCD policies at all transplant centers, and the Joint Commission on the Accreditation of Healthcare Organizations required all hospitals to have a DCD policy in place as of January 1, 2007.

To assist facilities in the development of consistent and appropriate policies, the Task Force analyzed the history of DCD, reviewed available literature, and examined the ethical propriety of DCD. Key points in the ethical analysis include the following:

- Decisions to withdraw and withhold life-sustaining treatment should be made independently from any consideration regarding organ and tissue donation;
- Policies should explicitly differentiate the process of withdrawing and withholding life sustaining treatments, the declaration of death by cardiopulmonary criteria, and the retrieval of organs;
- Health professionals with ethical objections to the practice of DCD should be allowed to decline to participate, and
- The provision of compassionate end of life care for the patient, and appropriate support for the family, should be a critical aspect of the DCD protocol.

The Department concurs with the ethical analysis of DCD and accepts each of the recommendations contained in Section III of the report. Specifically, the Department endorses the following:

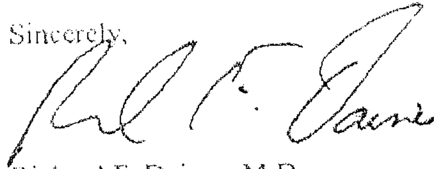
1. A health care agent, appointed pursuant to Article 29-C of the Public Health Law, is authorized to consent to appropriate pre-mortem DCD procedures (as those procedures are defined in the attached report);

2. The administration of heparin pre-mortem is permissible for DCD; and

3. A 5-minute waiting period between cardiopulmonary arrest and the declaration of death is appropriate for use in DCD protocols.

I urge you to consider the recommendations made by the Department and Task Force in establishing the DCD policy for your facility. If you have any questions, you may contact Kelly Pike, Principal Policy Analyst for the New York State Task Force on Life & the Law, at 212-417-5972 or via email at [illegible].

Sincerely,



Richard F. Daines, M.D.
Commissioner
New York State Department of Health

Enclosure

Donation After Cardiac Death: Analysis and Recommendations from the New York State Task Force on Life & the Law

Introduction

The scarcity of organs for transplantation, an ongoing crisis, has inspired many initiatives to increase supply. Within this context, donation after cardiac death (DCD) is receiving considerable attention. Of note, the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) required all hospitals to develop policies for DCD, effective January, 2007.[1] Similarly, the United Network for Organ Sharing (UNOS) proposed new bylaw amendments requiring all transplant centers and Organ Procurement Organizations (OPOs) to develop DCD policies by January 1, 2007.[2] In response to these initiatives, hospitals in New York and around the country are creating DCD policies. To assist in the development of consistent and appropriate policies for DCD, a 2005 national conference of transplant professionals, bioethicists and others reviewed issues related to DCD and formulated consensus guidelines.[3]

However, even as DCD gained acceptance, it has engendered controversy. Some practitioners express reservations about the ethical propriety of various aspects of DCD. As a result, individual facilities invest considerable time and effort to devise policies that address the interests and concerns of patients, families, and practitioners. Many facilities request guidance in crafting appropriate and consistent guidelines that address both ethical questions and specific issues within New York law.

This Task Force report provides ethical and clinical guidance for facilities in New York that are drafting and/or reviewing policies for DCD. It reviews the history of DCD, describes the DCD process, analyzes areas of legal and ethical tension within the practice of DCD, and attempts to resolve those tensions. The document includes specific recommendations for clarifying legal and ethical issues related to DCD in New York.

History of Donation After Cardiac Death

Nobel Laureate Dr. Joseph Murray performed the first human organ transplant at Peter Bent Brigham Hospital in 1954. In this transplantation, Ronald Herrick donated a kidney to his identical twin, Richard, who lived for another 8 years post-transplant. Transplantation might have remained a novelty if it could only serve identical twins, one with a failing organ and another with a spare and healthy organ. Shortly after Murray's initial success, however, physicians sought to expand the applicability of transplantation both by overcoming the hurdle of organ rejection and by identifying additional sources of organs.

Transplantation pioneers began to use organs from live donors other than identical twins, as well as from recently deceased patients. Daunting technical difficulties emerged, regarding both immune suppression and organ viability, as the donor pool expanded beyond living identical twins. Yet less than a decade after Murray's ground-breaking effort, Dr. Thomas Starzl and others reported a series of 12 renal transplants using various methods to decrease rejection and increase organ function; 10 organs came from live donors and 2 from deceased donors.[4] Among the recipients from living donors, 9 patients survived; both recipients of organs from deceased donors died. Of note, all deceased donors during those early years met

cardiopulmonary criteria for death, the only standard then in existence. Early experiments using donation after cardiac death proceeded without ethical reservation. However, transplantation of organs from these early donors after cardiac death produced disappointing results. Transplant pioneers met with greater success through the emerging practice of donation after brain death.

Determination of Death: In 1968, the Ad Hoc Committee of Harvard Medical School established the standard for brain death, defined as "the irreversible cessation of all brain function."[5] The clinical indicators of brain death include coma, lack of brainstem reflexes, and apnea. The Ad Hoc report prompted legislatures around the country to clarify the legal status of brain death. New York State relied upon case law to confirm the legal validity of brain death.[6] New York's Department of Health produced voluntary guidelines for the assessment of brain death, most recently revised in 2005.[7] In contrast to neurologic criteria for death, the cardiopulmonary criteria are the irreversible cessation of heart and lung function. Patients who meet either cardiopulmonary or brain death criteria are legally dead; both sets of criteria are valid ways to document the same state.

Brain death is a function of modern technology. In brain death, all aspects of brain function have failed, including the brain apparatus that maintains breathing; without a ventilator a brain dead person's lungs do not function and the person will meet cardiopulmonary criteria for death. When brain dead persons are attached to ventilators, continued oxygenation may temporarily preserve the viability of organs. In contrast, patients who meet cardiopulmonary criteria for death lack heartbeats and respiration; by definition their organs are not supported by ventilators and receive neither blood flow nor oxygenation.

Prior to the introduction of the Harvard Brain Death criteria, organs were recovered only from living donors or individuals meeting traditional cardiopulmonary criteria for death. Following the establishment and acceptance of the neurological criteria for death, donation after brain death became far more common in the U.S. than donation after cardiopulmonary death. Organs from brain dead donors suffered less trauma and produced better outcomes than those from donors after cardiac death. Moreover, brain death standards permitted the recovery of organs, including hearts, which are difficult to obtain via donation after cardiac death due to their great sensitivity to ischemia. Importantly, it was the technical superiority of the recovered organs that drove the move away from donation after cardiac death and toward brain death, rather than ethical reservations about DCD.

Institute of Medicine Reports: In 1997, the Department of Health and Human Services (HHS) requested that the Institute of Medicine (IOM) review ethical and technical aspects of DCD (then known as "non-heart beating organ donation"). Both health policy and transplantation experts were alarmed at the shortage of organs for transplant, and hoped to increase supply. In addition, controversial information emerged regarding the practice and meaning of DCD. Specifically, a bioethicist in Ohio learned of a proposed DCD protocol at the Cleveland Clinic and was convinced that the process involved euthanasia to obtain organs.[8] Rather than review her concerns with officials at the Cleveland Clinic, she met with the local district attorney and also appeared on the television show *60 Minutes*; this controversy occurred just prior to HHS' request to IOM to assess ethical and clinical aspects of DCD.

Far from condemning DCD, the IOM produced two separate reports, in 1997 and 2000, that define and support the process.[9] The 1997 report notes that the contemporary practice of DCD depends upon appropriate policies for and acceptance of the withdrawal of life-sustaining treatments such as mechanical ventilation. The report describes the increased attention to DCD

in the 1990's at leading transplant centers such as those at the University of Wisconsin at Madison and Pittsburgh. The report also includes a review of all known DCD policies at the time of publication. The protocols varied in significant ways as facilities worked to resolve tensions surrounding this end-of-life procedure. These same issues concern facilities that are currently devising DCD protocols. Policies vary regarding the permissibility and timing of specific interventions, including the use of medications, including heparin, the insertion of cannulae into donors before death, and the period of time elapsed between cardiac arrest, declaration of death, and organ retrieval.

The 2000 IOM report was commissioned by HHS to provide guidance for organ procurement organizations (OPOs) in developing appropriate procedures for DCD. IOM staff reviewed and analyzed changes in protocols since the publication of the 1997 report, and noted impediments to DCD.

Institute of Medicine Report: Recommendations

- All Organ Procurement Organizations (OPOs) should explore DCD in cooperation with local hospitals, health care professionals, and communities. A protocol must be in place in order for DCD to proceed.
- The decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation.
- Statistically valid observational studies of patients after the cessation of cardiopulmonary function need to be undertaken by appropriate experts.
- DCD should focus on the patient and the family.
- Efforts to develop voluntary consensus on DCD practices and protocols should be continued.
- Adequate resources must be provided to sustain DCD in order to cover the costs of outreach, education and support for OPOs, providers and the public, as wells as any increased costs associated with DCD recovery.

Institute of Medicine Report: Obstacles to DCD Implementation

- Hospitals: lack of protocols, lack of interest, physician resistance
- OPO: limited financial and staff resources for training and outreach, limited technology and expertise
- Organs: concerns about organ quality, adequate organ supply without DCD donors
- Ethics: medical interventions, termination of life-sustaining treatment, determination of death

Technological improvements led to an increased capacity to preserve organ viability in the context of DCD. Certain centers continued to perform DCD even as donation after brain death became more common: these centers helped improve techniques.[10] In addition, the concept of brain death inspired substantial controversy in Japan, which did not adopt legal standards for brain death until 1997. Transplantation there relied upon live donation and DCD, contributing to the study and improvement of DCD techniques.[11]

Current Developments in Transplantation and DCD

Demand for transplantable organs continues to grow at a rate that far outstrips supply. In part, transplantation is the victim of its own success. Continued advances in fighting organ rejection and preserving function in transplanted organs make transplant an attractive option.

Both survival and quality of life are improved for patients after renal transplantation, as opposed to those who continue with dialysis.[12] There are many causes for the growing number of patients with end stage organ disease; contributing factors include increased rates of obesity, diabetes, and hypertension leading to renal failure. High rates of hepatitis C, in addition to cirrhosis and other factors, contribute to liver failure.[13] Medical advances, too, play a role. Many patients now survive life-threatening illnesses, such as heart attacks, yet do so with substantial chronic impairment. Significant resources have been devoted to promoting organ donation, and rates of donation are increasing as a result. However, wait lists continue to grow. Transplant advocates seek to maximize possible sources of organs, including those from brain dead donors with less than optimal, or extended criteria, organs.

Renewed focus on DCD forms part of a broader strategy to help resolve the shortage of organs for transplant. In recent years, the federal government has funded a series of large-scale projects called "Breakthrough Collaboratives" designed to support, improve, and expand various aspects of transplantation. Similarly, a number of public and private research institutions have directed considerable resources toward investigating new systems to promote donation. The Institute of Medicine's publication, *Organ Donation: Opportunities for Action*, reviews various methods to increase the number of organs for transplantation from both live and deceased donors.[14]

DCD Candidates

Organs for donation, either via DCD or brain death, must function sufficiently well to benefit a potential recipient. Patients who are not suitable donors include many with cancer and systemic infectious disease, as these conditions present serious medical hazards to immunosuppressed recipients. Organ function decreases with age, and thus some older patients are not suitable donors. Irrespective of whether patients will meet neurologic or cardiopulmonary criteria for death, candidates for donation represent a minority of terminally ill patients.

Candidates specifically for DCD "include patients whose life-sustaining treatment is under consideration for withdrawal and who will likely die soon after the withdrawal/refusal of this treatment."[15] Conditions leading to DCD candidacy include irreversible brain injury, end-stage musculoskeletal disease and severe spinal cord injury.[16] Other possible candidates include those who rely upon ventilators and other life-sustaining interventions, and who decide to withdraw treatment for reasons unrelated to organ donation. DCD candidates often closely approximate patients who meet brain death criteria, yet without fully meeting all prerequisites.

DCD Organs

Different organs tolerate different periods of reduced blood flow; therefore, technical challenges and success rates of DCD vary for different organs. For renal transplants, DCD organs currently provide comparable results to those from brain dead donors, and at times better results than from extended criteria donation (ECD) by brain dead donors.[17] DCD liver transplants offer mixed results: some experts report "excellent" outcomes.[18] However, others note the liver's increased susceptibility to warm ischemic time, the period of low or absent blood flow prior to organ retrieval; prolonged warm ischemic time can result in decreased liver function.[19] However, patients with end stage liver disease lack the option of a bridge therapy

like dialysis. Due to the shortage of organs, their choice is often between an imperfect liver and no liver, rather than between imperfect and optimal organs.[20] DCD lung transplantation is a new and evolving practice.[21] DCD heart transplant remains rare due to the heart's extreme sensitivity to ischemia, but some experts anticipate the development of this practice.[22]

Process of Donation After Cardiac Death

The complex process of DCD may vary in some particulars, but basic procedures are substantially the same; variants and related ethical issues are noted. In all cases, staff members who find DCD ethically objectionable are allowed to excuse themselves from participation in the procedure. The process of DCD includes these steps:

- Decision to withdraw treatment
- Assessment for DCD
- Withdrawal of treatment
- Pre-mortem interventions
- Cardiac arrest and organ retrieval

1. Decision to Withdraw Treatment. Advocates of DCD, including the IOM, insist upon a clear separation between the decision to withdraw life-sustaining treatment and the decision to donate organs. A patient who retains decision-making capacity could decide to terminate life-sustaining treatment and to subsequently donate organs through the process of DCD. In these cases where the patient personally provides informed consent for DCD, there are few ethically complex issues. However, first person consent is quite rare in the context of DCD. Far more commonly, a patient has suffered a profound loss of cognitive capacity and others must make the decision on behalf of the patient. If the patient appointed a proxy while still capable, the proxy can determine whether withdrawal of treatment honors the patient's previously expressed wishes or best interests. If the patient has not appointed a proxy, New York law requires that a surrogate decision-maker rely upon "clear and convincing evidence" of the patient's wishes in order to terminate life-sustaining treatment.[23]

The option of donation is not raised in advance of the decision to withdraw treatment for fear that this might inappropriately hasten withdrawal. In some cases, family members raise the issue of donation; in these situations the family is encouraged to make the decision about withdrawal of treatment first and then decide about donation. After the decision to withdraw treatment, the hospital contacts the OPO, and then organ donation representatives review the patient's clinical condition to see if donation after cardiac death is possible (medical factors such as systemic infection and advanced age preclude organ donation). If the patient is a potential candidate, the donor coordinator will then approach the family to discuss donation. Seeking consent for DCD includes an explanation of the process and an opportunity for the family to ask questions. The family must understand that a number of factors may prevent DCD, including failure to reach cardiac arrest within a specified period after respirator removal.

2. Assessment for DCD: If the patient or authorized surrogate decision-maker wishes to pursue the option of DCD, the organ donation representative will further assess the patient. A critical factor in determining suitability is the expected duration of respiration and heartbeat after the ventilator is withdrawn. Some patients do not breathe at all without assisted ventilation, and cardiac arrest ensues rapidly. Other patients will continue respiratory efforts for a prolonged period; this degree of respiration may be insufficient to sustain life but can delay cardiac arrest

for hours or days. Organs deteriorate after a prolonged period of low blood flow and/or low oxygenation; an extended period of relative ischemia or hypoxia will render organs unusable.

Assessment of DCD potential requires a trial of weaning from the ventilator to measure the patient's capacity for spontaneous breathing, the inspiratory force of such efforts, and their efficacy in maintaining oxygen saturation in the blood. Such an assessment of respiratory capacity is neither inappropriate nor uncommon when withdrawal of the ventilator is planned. Often, the assessment clarifies whether withdrawal is appropriate and how the process will unfold, even for patients who are not potential donors. However, since trial weaning could destabilize a ventilator-dependent patient, the surrogate decision-maker should give explicit consent for this procedure as part of the DCD process.

Researchers from the University of Wisconsin have devised an assessment tool that estimates the duration of time between removal of the ventilator and cardiac arrest.[24] This tool assigns points for various measures, including the patient's rate of spontaneous respirations, age, and dependence upon medications to support blood pressure. If the assessment indicates that cardiac arrest will occur within one to two hours after cessation of treatment, the patient is deemed a suitable candidate for DCD. Not all facilities rely upon the Wisconsin assessment tool; some doubt its predictive reliability while others worry that it may inappropriately increase risk for patients since supplemental oxygen is not used during the assessment. Some facilities assess respiratory capacity by the same protocol that is used in the assessment of brain death.

3. Withdrawal of Treatment: Whenever withdrawal of life-sustaining treatment is planned, a patient must have an order not to resuscitate (DNR). Without such an order, physicians attending the dying patient would face a paradoxical obligation to reinsert the ventilator tube and provide other interventions as well. With a DNR order in place, in contrast, health professionals must not attempt any resuscitative interventions because consent is explicitly denied in the order. A DNR order is needed for the process of withdrawing treatment that precedes and forms part of the DCD process.

Patients who are candidates for DCD are generally transferred to the operating room (OR) for withdrawal of treatment. Some facilities permit the patient to remain in the intensive care unit until cardiac arrest, in an effort to ease barriers to DCD both for families and staff.[25] However, transfer of the patient after cardiac arrest may result in delays that cause deterioration of the organs and undermine the intent to donate. In some facilities the family may accompany the patient in the OR during the cessation of life-sustaining treatment and while awaiting cardiac arrest. The family must agree to leave the OR immediately after arrest or donation cannot occur.

Hospital policies vary as to which physician should take responsibility for the withdrawal of the ventilator. Often the patient's attending physician performs this task. In some cases the anesthesiologist in the OR supervises withdrawal of the ventilator, though some anesthesiologists raise ethical objections to this practice.[26]

If a patient meets eligibility criteria and begins the process for withdrawal with the intent to donate, yet does not progress to cardiac arrest within the designated time limit (usually one hour), then the patient will not become a donor and will return to the intensive care unit or other suitable ward for comfort measures and appropriate care. Patients would not at that point be re-intubated, unless in the unusual circumstance of a specific request from the surrogate decision-maker. This eventuality would need to be discussed with the family as part of the consent process for DCD.

4. Pre-mortem Interventions. Various interventions may increase organ viability; interventions after the death of the donor generally do not pose ethical problems. Individual

clinicians and facilities reach different conclusions about the ethical propriety of interventions before the patient's death that are intended to benefit the organ recipient. Hospital policies vary considerably as to which interventions are permitted. Some facilities, consistent with the advice of the IOM reports, permit the pre-mortem installation of catheters in the patient's leg; these can be used to rapidly instill cooling and preserving fluids after the patient's demise. Other facilities permit the use of a range of medications, including those that may lower the patient's blood pressure, or heparin, which helps prevent the formation of blood clots. Issues related to pre-mortem interventions are discussed in the Legal and Ethical Issues section of this report.

5. Cardiac Arrest and Organ Retrieval: Once the ventilator and other life-sustaining treatments are withdrawn, the patient receives palliative care according to the facility's policy. Pain medication or other measures comfort the dying patient; this period may last up to two hours depending on local protocol. Once respiration stops completely, cardiac arrest must be documented. For the purposes of DCD, cardiac arrest is determined by 1) the absence of a palpable pulse; and 2) electrocardiographic changes such as pulseless electrical activity that indicate the absence of heart function. After the determination of cardiac arrest, clinicians must wait a prescribed period, from two to ten minutes, depending on the local protocol. This waiting period is intended to guarantee that the patient's heart is no longer capable of spontaneously resuming contractions. The appropriate duration of this waiting period has received much discussion. After cardiopulmonary arrest and the subsequent waiting period, the physician declares the patient dead by cardiopulmonary criteria. A different set of physicians, not responsible for declaring death, will then proceed with organ retrieval.

Legal and Ethical Issues

Several legal and ethical issues arise in relation to DCD; many are associated with aspects of surrogate consent. (Issues related to the determination of death also arise and will be discussed subsequently.) Patients who retain decision-making capacity have a clearly established right to request that life-sustaining therapies be withdrawn or withheld. Similarly, patients with capacity may consent to donate organs after their demise, including through DCD. There are relatively few legal or ethical problems related to DCD for patients with decision-making capacity, although even these patients may not request measures that actively hasten death. However, patients with decision-making capacity who are potential DCD candidates are rare; most potential DCD candidates have lost decision-making capacity and someone else must act on their behalf.

I. Surrogate Consent for DCD

Laws governing surrogate consent for various health-related matters in New York are complex and often conflict with one another; New York's legal standard for surrogate healthcare decision-making has been described by scholars as "unworkable."[27] Different, often contradictory, laws govern surrogate decisions in the following circumstances: 1) orders not to resuscitate; 2) health care decisions made by appointed agents; 3) health care decisions made when no appointed surrogate exists; and 4) organ donation. The DCD process may require consent under a number of these laws. This complex regulatory thicket may assign competing authority to different persons making different decisions during the process of DCD. Actual instances of conflict are not common since many patients either have only one person to speak on their behalf, or all concerned parties are in agreement.

DCD includes multiple procedures, both pre- and post-mortem. Ethically relevant aspects of the surrogate consent process exist for each of these elements of DCD:

- Orders not to resuscitate
- Decisions to withdraw life-sustaining treatment
  - By designated health care agents
  - Without a designated surrogate
- Pre-mortem procedures
- Organ donation

Orders Not to Resuscitate: A DNR order must be part of the process of DCD; life-sustaining treatment will be withdrawn, allowing the patient to expire without efforts at resuscitation. New York Public Health Law section 2965 governs consent to an order not to resuscitate (DNR order), including consent by a surrogate. Except when an adult patient consented to a DNR order before losing decision-making capacity, clinicians must obtain surrogate consent before issuing such an order. If neither the patient nor a designated health care agent can provide consent, a person from the following list, chosen in order of priority listed, has the authority to consent to a DNR order on behalf of the patient:

- a person appointed by a court to manage the personal affairs of an adult who is incompetent, developmentally disabled, or mentally retarded;[28]
- the spouse;
- a son or daughter 18 or older;

- a parent;
- a sibling 18 or older;
- a close friend.

New York law also provides for the issuance of a DNR order by a physician on behalf of the patient when no one from the above list is available, and when other specific conditions are met.[29]

Withdrawal of Life-sustaining Treatment via Health Care Agents: Under New York law, a patient's authorized health care agent can make decisions regarding health care, including withdrawal of life-sustaining treatment, in accordance with the patient's known wishes, or in the patient's best interests if his/her wishes are not known.[30]

Withdrawal of life-sustaining treatment without a designated surrogate: Most patients in New York have not appointed a health care agent; when such patients lose decision-making capacity, New York case law requires "clear and convincing" evidence of the patient's wishes in order to withhold or withdraw life-sustaining treatment. This unusually high standard of evidence puts New York in a tiny minority among the states, and serves as a barrier to health care decision-making in a wide range of contexts. For more than a decade, efforts to address this gap in New York law have focused on passage of the Family Health Care Decisions Act. However, New York has not succeeded in passing the Act, despite widespread support from a broad range of professional and civic groups. Without the Act, New York lacks a mechanism for making reasoned decisions for that majority of incapacitated patients who have neither appointed an agent nor spoken in sufficient detail about the circumstances of their demise to satisfy the legal standard. There is no established hierarchy among family members and friends who might wish to help make decisions for their loved one, and no mechanism for acting in the patient's best interest, in the absence of specific commentary from the patient on end of life treatment. [31]

Pre-mortem DCD procedures: A number of different pre-mortem procedures are included in DCD protocols; considerable variability exists among DCD policies about the use of pre-mortem procedures. These procedures potentially include: 1) the insertion of large intravenous catheters or cannulae to facilitate the post-mortem administration of fluids that preserve organs; 2) medications that increase organ viability by increasing vasodilation (enlarging blood vessel diameter); and 3) medications that increase organ viability by preventing clotting.

Some question the right of health care agents to make decisions about pre-mortem interventions that form part of the DCD process. This argument focuses primarily on the specific language regarding the definition of health care in New York's proxy statute. The proxy law defines a "health care agent" as an adult to whom a patient delegates the "authority to make health care decisions."[32] A "health care decision" is defined as "any decision to consent or refuse to consent to health care."[33] "Health care," in turn, is defined in the law as "any treatment, service, or procedure to diagnose or treat an individual's physical or mental condition."[34] Thus, this argument holds that decisions about interventions to promote organ viability are not intended to help diagnose or treat the patient, and are therefore not health care decisions. (Proxies clearly can and do provide consent for the same interventions, such as the use of heparin, at other points in the patient's treatment.) If correct, the argument that pre-mortem decisions related to DCD are not health care decisions would effectively prevent DCD in New York; it would mean that not even the health care proxy could consent to pre-mortem interventions that promote organ viability. Of note, this argument does not have an impact on DCD discussions in other states or

nationally.

Moreover, others argue that this line of reasoning ignores important aspects of both health care and surrogate decision-making. Patients appoint health care agents because they know that not all potential decisions can be foreseen, and so can neither be discussed with loved ones nor included in a document such as a living will. This problem particularly affects novel interventions and practices, including DCD, that were not known options at the time the advance directive was written. The core function of a health care agent is to uphold the patient's preferences and values in making future health care decisions. In appointing a proxy, patients indicate that they trust this person to define their best interests and uphold them. A restrictive reading of the definition of "health care" countermands the specific intent of the patient in appointing a proxy, and thus stands in opposition to the intent of the law. New York's proxy law was explicitly designed to provide robust decision-making powers for the health care agent, as its legislative history makes clear. For example, the Task Force's influential 1987 report, *Life-Sustaining Treatment: Making Decisions and Appointing a Health Care Agent*, notes that the appointment of an agent "enhances the individual's ability to direct health care matters in accordance with personal concerns, values, and life goals."[35]

In addition to the question of whether decisions relevant to DCD constitute health care decisions, one might question whether such decisions are made in the patient's best interest, as the agent is instructed to act when the patient's wishes are unknown. A definition of best interest that includes promoting the patient's values and goals will lead to the inclusion of decisions related to DCD within the purview of the health care agent.

Pre-mortem Catheterization: The issue of the patient's best interest overlaps with that of consent to pre-mortem interventions, especially when such procedures might pose a risk to patients. We analyze the ethical issues related to three proposed pre-mortem procedures: the insertion of additional catheters, the administration of anticoagulants and/or the administration of vasodilating medications. Large-bore catheters, or cannulae, are sometimes inserted in advance of the patient's demise into major vessels such as leg veins in order to rapidly supply cooling and preserving fluids upon the patient's death; these fluids help preserve organ viability. The insertion of a catheter in an alert patient could be painful; analgesia is generally used if there is any possibility that a patient could feel pain during this procedure. The 1997 IOM report found that this procedure is ethically appropriate but that family members should provide explicit consent for it. Some major transplant centers follow this policy. Nonetheless, even if pain is controlled, some view pre-mortem insertion of a cannula as an unacceptable burden on the dying patient. In addition, this procedure is not considered essential for organ preservation. Various facilities in New York that permit DCD do not include pre-mortem cannulation in their protocol.

Vasodilators and Anticoagulants: Different medications can promote organ viability, for instance by preventing clots or increasing vasodilation. As noted in the 1997 IOM report, protocols at that time varied widely, with some prohibiting either type of medication, some permitting both, some permitting their use pre-mortem, but others only permitting administration after cardiac arrest or after declaration of death.[36] Medication that dilates vessels can help preserve organ viability but may also lower the patient's blood pressure and hasten demise. Facilities vary regarding the permissibility of pre-mortem administration of vasodilators in their protocol. No expert consensus exists currently as to the technical necessity of pre-mortem use of vasodilating medication.

In contrast, experts agree that heparin is a critical component of DCD. Transplant professionals at a national consensus conference stated that, "the administration of heparin at the

time of withdrawal of life-sustaining treatment is the current standard of care and a key component of best practice."[37] Many transplant surgeons fear that organs without heparin will not function and therefore will not accept DCD organs unless heparin has been administered. Thus, elimination of heparin from DCD protocols might render the process unworkable. However, not every successful DCD donation includes the pre-mortem use of heparin.[38]

Questions about the use and timing of heparin can present a barrier to the adoption of DCD policies, as clinicians worry that this medication may actively speed the demise of the patient. In response, transplant physicians note a lack of supporting data to show that heparin hastens death. Indeed, most intensive care patients are already treated with heparin as part of their medical care. Moreover, it is the patient and/or surrogate's decision to withdraw life-sustaining treatment that permits the underlying pathology to cause death: death is neither an unexpected nor an unwanted outcome in this process. However, all agree that actively hastening death is not the goal.

Third-party consent to organ donation: New York law authorizes third-party consent for organ donation by next of kin and others. New York's Anatomical Gift Act designates the following priority list of individuals who can consent to donation of a deceased individual's organs, assuming the deceased never expressed contrary wishes:

- Spouse
- Child (18 or over)
- Parent
- Sibling (18 or over)
- Legal guardian
- Person authorized to dispose of the body

A health care agent can consent to organ donation only if he/she also fits one of the above categories. As the proposed DCD protocol of one New York hospital cautions, "The Health Care Proxy is not authorized to give consent unless THAT INDIVIDUAL APPEARS IN THE LIST ABOVE." (emphasis in original). Though the Anatomical Gift Act authorizes consent for donation, it clearly does not authorize the donation surrogate to consent to withdrawal of treatment.[39]

Potential conflicts in surrogate decision-making: As noted above, the health care proxy is not listed among those who can consent to organ donation; this omission derives from the fact that the donation law preceded the existence of the proxy legislation. Further, the surrogate priority list for organ donation differs from the priority list for DNR orders, creating additional potential for conflict in surrogate decision-making for the DCD process. New York's statutes and standards for surrogate end-of-life decisions present a series of conflicting priority lists and procedures. Irrespective of the creation of DCD policies, harmonization of these standards would improve the decision-making process for these vulnerable patients.

The Task Force encourages New York State to develop legislation that will harmonize priority lists for statutes related to end-of-life decision-making. These statutes include, but are not limited to:

i. Health Care Proxy Law (Public Health Law Article 29-C)
ii. Anatomical Gift Law (Public Health Law Article 43)
iii. DNR Law (Public Health Law Article 29-B)

II. Determination of death

The determination of appropriate intervals between cardiopulmonary arrest, declaration of death, and organ retrieval within the DCD process has been a topic of vigorous debate. Variations in facility policies were noted in the IOM report, as well as in the transplant literature. The briefest interval between arrest and declaration was one minute; other facilities waited as long as ten minutes. After death is declared, organ retrieval proceeds without delay. The challenge is to find the duration that best guarantees that cardiorespiratory function cannot resume, while still preserving organ viability. Both the IOM and the National Conference report recommended five minutes as an appropriate pause.

Dead donor rule. The transplant community supports a general principle known as the dead donor rule, which dictates that patients must be declared dead before their organs are removed. In the DCD context, the phrase "donation after cardiac death" itself explicitly states a timeline: death, then donation.[40]

While some theoreticians have debated the wisdom of this principle, the dead donor rule is unequivocally reflected in New York law, which states that an anatomical gift "take[s] effect upon death."[41] Like any cadaveric donation, a DCD organ would be an anatomical gift, and therefore subject to this statutory form of the dead donor rule.

Legal definition of death. Under New York law, a person is defined as dead when they meet either one of two sets of criteria: "(1) irreversible cessation of circulatory and respiratory functions; or (2) irreversible cessation of all functions of the entire brain, including the brain stem."[42] It is the first of those two standards that characterizes the DCD donor.

The Anatomical Gift law also reflects these two methods of determining death:

> When a donor is determined dead based on irreversible cessation of circulatory and respiratory functions, the time of death shall be certified by a physician.... In all other cases the time of death shall be certified by the physician who attends the donor at his death and one other physician....[43]

Although the law provides a legal definition of cardiopulmonary death—"irreversible cessation of circulatory and respiratory functions"—neither statute nor regulation defines "irreversible" or specifies the moment when irreversible cessation occurs.

Isolating this precise moment is rarely important. In DCD, however, timing is crucial, as clinicians must adhere to the dead donor rule while recognizing the time-limited viability of organs. As the first IOM report states, "A little more time can make the diagnosis [of death] obvious, but, in donors, may result in organs of poor or unstable quality."[44] Scholars such as Jerry Menikoff are concerned that DCD may thus create an incentive to "'rush' the process of declaring death."[45]

As described in the 2000 IOM report, "irreversible" can have one of several meanings: "(1) will not resume spontaneously; (2) cannot be started with resuscitation measures; (3) will not be restarted on morally justifiable grounds."[46] IOM, like the transplant community, chose a hybrid definition, selecting the first and third meanings above and leaving aside the second. They conclude that "death occurs when cardiopulmonary function will not resume spontaneously and will not be restarted artificially."[47] This definition does not include the troubling second possible meaning, that heart and lung function simply cannot be restarted, including by medical

intervention. This aspect of the definition is left aside because it may not be literally true in at least some cases of DCD. We have limited data on the outside limit of time after which a heart could resume function with vigorous intervention. Moreover, when DCD lungs are removed from the donor, the cessation of pulmonary function is reversed. The same would apply in the case of cardiac function for DCD donors, though substantial technical barriers to cardiac DCD exist.

This problem of defining the moment of death applies not only in the case of DCD, but also with all instances of the planned and consensual withdrawal of life support. The patient is declared dead when heart and lung function cease. No attempts will be made to restart such function, because permission for resuscitation is explicitly denied in the DNR order. Thus, all declarations of death for DNR patients define "irreversible" to mean that cardiopulmonary function will not spontaneously resume, and that physicians are not permitted to attempt resuscitation.

Menikoff calls the IOM definition "moral" irreversibility.[48] An opposing definition would be "scientific" irreversibility, whereby "cardiopulmonary function is not *irreversibly* lost as long as it could conceivably be restored by vigorous resuscitation efforts."[49] As noted, medical evidence is inconclusive regarding the maximum time without blood flow and oxygen that might still permit resuscitation. Attempts to rely upon the second definition could invalidate the 5-minute threshold as a marker for the dead donor rule.

Expert consensus currently supports use of the 5-minute waiting period between arrest and declaration of death; the Task Force also supports a 5-minute interval. This standard derives from a review of available evidence by IOM, and has been reiterated in guidance issued by UNOS as well as by organizations of transplant professionals.[50]

III. Task Force Recommendations

After this thorough review of existing literature and analysis of relevant laws and regulations, the Task Force crafted the following set of recommendations to assist facilities in New York State in developing DCD policies. These recommendations provide ethical guidance in an effort to assure that policies are consistent and appropriate.

1. **Surrogate consent for DCD**
   - Hospital DCD policies should clarify that health care agents are authorized to consent to pre-mortem DCD procedures, to the extent that these procedures are consistent with the patient's known wishes and/or best interests, as understood by the health care proxy.

2. **Pre-mortem treatment**
   - Hospital policies should support the use of heparin, but should not currently support the insertion of additional catheters pre-mortem, or the addition of medications solely for the purpose of vasodilation to promote organ preservation.

3. **Declaration of Death**
   - Hospital policies should support the imposition of a 5-minute waiting period between cardiopulmonary arrest and the declaration of death in DCD protocols.

Conclusion

The current practice of DCD constitutes the reemergence of a practice from the earliest days of transplantation, yet with attention to contemporary standards of end-of-life care. Both the Joint Commission and UNOS required that facilities have DCD policies by January 2007. This Task Force document analyzes challenging issues within the process of DCD, and presents recommendations to address legal and ethical tensions. As DCD becomes more common in New York, NYS DOH and health care facilities may wish to collaborate in collecting data that will help identify best practices regarding consent, pre-mortem interventions, declaration of death, and the medical and other impact on patients, their families and providers. The Task Force hopes that these recommendations will permit hospitals to include DCD among the options that support patient preference in end-of-life care.

---

[1] JCAHOnline, "Revised organ procurement and donation standard," June 2006. Website: http://www.jointcommission.org/Library/JCAHOnline/jo_06_06.htm, accessed October 30, 2006.
[2] "Highlights of the June Board Meeting," *UNOS Update*, July-August, 2006: 3.
[3] J. L. Bernat, A. M. D'Alessandro, T. P. Port, et al., "Report of a National Conference on Donation After Cardiac Death," *American Journal Transplantation*. 2006, 6:281-291.
[4] T. Starzl, T. Marchioro, R. Brittain, et al. "Problems in Renal Homotransplantation," *Journal of the American Medical Association*. 1964.187(10):734-740.
[5] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academies Press, 2000, 25.
[6] New York State Task Force on Life & the Law, *The Determination of Death*. NYS DOH, 1986.
[7] New York State Department of Health, "Guidelines for Determining Brain Death," NYS DOH, 2005.
[8] G. Kolata, "Controversy erupts over organ removal," *The New York Times*. April 13, 1997.
[9] IOM, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, National Academies Press, 1997. IOM, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academies Press, 2000.
[10] 1997 IOM report, 23.
[11] M. Nishikido, M. Noguchi, S. Koga, et al., "Kidney Transplantation from non-heart-beating donors: analysis of organ procurement and outcome," *Transplant Proceedings* 2004;36(7):1888-90.
[12] R. A. Wolfe, V. B. Ashby, E. L. Milford, et al., "Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant," *New England Journal of Medicine*. 1999;341:1725.
[13] R. Stribling, N. Sussman, J.M. Vierling, "Treatment of Hepatitis C Infection," *Gastroenterologic Clinics of North America* 2006;35(2):463-86.
[14] Institute of Medicine, Committee on Increasing Rates of Organ Donation, J.F. Childress and C.T. Liverman, *Organ Donation: Opportunities for Action*; National Academies Press, 2005 (prepublication).
[15] Bernat, 282.
[16] Bernat, 282.
[17] Bernat, 285.
[18] L. Olson, J. Kisthard, J. Fung, et al., "Livers transplanted from Donors after cardiac death occurring in the ICU or the operating room have excellent outcomes." *Transplantation Proceedings* 2005:37:1188-1193
[19] Bernat, 284. P. Abt, M. Crawford, N. Desai, et al., "Liver Transplantation from controlled non-heart beating donors increase incidence of biliary complications." *Transplantation* 2003: 75(10):1659.
[20] New York State Department of Health Workgroup, "Workgroup on Expanded Criteria Organs for Liver Transplantation, *Liver Transplantation*. 2005; 11(10):1184-92.
[21] G. I. Snell, T. Oto, B. Levvey, et al. "Evaluation of techniques for lung transplantation following donation after cardiac death," *Annals of Thoracic Surgery*. 2006:81(6):2014-9.
[22] Bernat, 285.

[23] Decisions regarding administration of artificial nutrition and hydration may be made only if the patient's wishes are known or can be ascertained. § 2982(2). New York State law permits a formally designated proxy to make surrogate decisions for patients who lack capacity based on the patient's wishes, if known, or best interests in other cases. A significant gap in New York law, making it highly unusual among the states, requires non-designated surrogate decision-makers to rely upon "clear and convincing" evidence of a patient's wishes. Thus, for patients without formal advance directives, or designated proxy deciders, or this high level of evidence, decisions to withdraw treatment are problematic. The majority of patients in New York today lack proxies and sufficient evidence of their wishes. The proposed Family Health Care Decisions Act would resolve this significant problem but has failed to pass in the New York State Legislature.
[24] J. Lewis, J. Peltier, H. Nelson, et al., "Development of the University of Wisconsin donation after cardiac death evaluation tool," *Progress in Transplant* 2003:13:265-73.
[25] Olson.
[26] G. A. Van Norman, "Another Matter of Life and Death: What every anesthesiologist should know about the ethical, legal and policy implications of the Non-Heart-beating cadaver organ donor." *Anesthesiology*. 2003: 98(3):763-73.
[27] T. Miller, T. Powell, J. Arras, et al., "Panel Discussion: Current Work of the Task Force— The Family Health Care Decisions Act and Directed Live Organ Donation." *NYSBA Health Law Journal* 2005;10(3):24-36.
[28] Specifically, the statute defines this person of first priority as: "a committee of the person or a guardian appointed pursuant to article seventeen A of the surrogate court's procedure act." In addition, this provision of the DNR law "shall not be construed to require the appointment of a committee of the person or guardian for the purpose of making the resuscitation decision."
[29] Public Health Law § 2966.
[30] Decisions regarding administration of artificial nutrition and hydration may be made only if the patient's wishes are known or can be ascertained. § 2982(2).
[31] See Miller, "Panel Discussion."
[32] Public Health Law § 2980(5)
[33] § 2980(6).
[34] § 2980(4).
[35] NYS Task Force on Life & the Law. *Life Sustaining Treatment: Making Decisions and Appointing a Health Care Agent*. NYS DOH.1987, p 90
[36] 1997 IOM report.
[37] Bernat, National Conference, 283
[38] Olson, 1190.
[39] Such an individual might provide clear and convincing evidence of the patient's wishes not to receive life-sustaining treatment, but that would be separate from their authority to consent to an anatomical gift.
[40] This chronology is not explicitly suggested in the DCD synonym "non-heart-beating organ transplantation."
[41] PHL § 4301(a).
[42] 10 N.Y.C.R.R. § 400.16.
[43] PHL § 4306(2). The law specifies that a physician certifying death under either criteria cannot participate in "the procedure to remove or transplant" an organ.
[44] 1997 IOM report, 57.
[45] J. Menikoff, "The Importance of Being Dead: Non-Heart-Beating Organ Donation." *Issues in Law and Medicine* 2002:18:3-20. Menikoff writes: "The desire to maximize the utility of the donated organs means that there is a pressure to minimize the time between the cessation of cardiac function and removal of the organs." Menikoff, 13.
[46] 2000 IOM report, 24.
[47] 2000 IOM report, 24 (citing 1997 IOM report).
[48] J. Menikoff, *Law and Bioethics*, Georgetown University Press, 2001, 464.
[49] 2000 IOM report, 24 (citing Menikoff).
[50] 2000 IOM report; Bernat, 28

NEW YORK STATE TASK FORCE ON LIFE & THE LAW

CHAIR
RICHARD F. DAINES, M.D.
Commissioner of Health, New York State

MEMBERS
KARL P. ADLER, M.D.; DONALD P. BERENS, JR., J.D.; RABBI J. DAVID BLEICH, PH.D.; KATHLEEN M. BOOZANG, J.D., L.L.M.; KAREN A. BUTLER, R.N., J.D.; NANCY NEVELOFF DUBLER, L.L.B.; PAUL J. EDELSON, M.D.; ALAN R. FLEISCHMAN, M.D.; REV. FRANCIS H. GEER, M.DIV.; SAMUEL GOROVITZ, PH.D.; JANE GREENLAW, R.N., J.D.; CASSANDRA E. HENDERSON, M.D.; KATHRYN C. MEYER, J.D.; JOHN D. MURNANE, J.D.; SAMUEL PACKER, M.D.; RABBI A. JAMES RUDIN, D.D.; BARBARA SHACK; DANIEL P. SULMASY, O.F.M., MD, PH.D.; ROGELIO THOMAS, M.D., M.P.P.; SALLY T. TRUE, J.D.

STAFF
TIA POWELL, M.D.
Executive Director
MICHAEL KLEIN, J.D
Counsel
KELLY C. PIKE, M.H.S.
Principal Policy Analyst
CANDACE DECAIRES-MCCARTHY
Administrator

A special thanks is also offered to the following former Task Force Members who contributed to this project: Rev. Msgr. John A. Alesandro, J.C.D., J.D., Saul J. Farber, M.D. Benjamn Gelfand, and Maria I. New, M.D.

NEW YORK STATE DEPARTMENT OF HEALTH

GUIDELINES FOR DETERMINING BRAIN DEATH

DECEMBER 2005

GUIDELINES
FOR DETERMINING BRAIN DEATH

BACKGROUND

These guidelines represent a broad consensus. They incorporate the guidelines of the American Academy of Neurology (AAN) and add recommendations for brain death determination in children. These guidelines also draw upon a consensus-building process in New York State that included convening a Brain Death Guideline Panel in November 2004, and review of the guidelines by the New York State Task Force on Life & the Law in 2005.

PURPOSE

The purpose of these guidelines is to provide health care providers with information about New York State requirements for determining brain death, increase knowledge amongst health care practitioners about the clinical evaluation of brain death, and reduce the potential for variations in brain death determination policies and practices amongst facilities and practitioners within New York State. The Department of Health hopes that the issuance of these guidelines not only will help educate health care providers regarding such determinations, but also will increase the public's confidence that such determinations are made after a thorough and careful evaluation in accordance with accepted medical standards.

DEFINITION

Brain death is defined as the irreversible loss of all function of the brain, including the brainstem (see 10 N.Y.C.R.R. § 400.16). The three essential findings in brain death are coma, absence of brainstem reflexes, and apnea. An evaluation for brain death should be considered in patients who have suffered a massive, irreversible brain injury of identifiable cause. A patient determined to be brain dead is legally and clinically dead.

The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including each of two assessments of brain stem reflexes and a single apnea test, are conclusively performed. In the absence of either complete clinical findings consistent with brain death, or confirmatory tests demonstrating brain death, brain death cannot be diagnosed.

Hospital Responsibilities Regarding Brain Death Determination

10 N.Y.C.R.R. § 400.16 requires all New York State hospitals to establish and implement written policies for determining brain death, including processes for:

- **Privileging physicians to make brain death determinations in accordance with accepted medical standards;**
- **Notifying the next of kin or other person closest to the patient that brain death determination is in progress;**
- **Providing reasonable accommodation of an individual's religious or moral objection to use of the brain death standard to determine death; and**
- **Determining brain death via appropriate clinical examinations and tests in accordance with accepted medical standards.**

Each of these responsibilities is addressed in further detail on the following pages.

Privileging

Each hospital should establish a process for identifying and privileging physicians to make brain death determinations. The application of the clinical criteria described in this policy requires the judgment of a physician competent in determining brain death. **Hospital policies may specify standards for training and assessing competency to determine brain death.** A physician need not be, or consult with, a neurologist or neurosurgeon in order to determine brain death.

The patient's attending physician should participate in the determination of brain death whenever possible. If the attending physician is not privileged by the hospital in the determination of brain death, another physician having such privileges must perform the assessment and make the final determination.

Notification

New York State law requires hospitals to make reasonable efforts to notify the next-of-kin or person closest to the individual that the process of evaluating brain death has begun. Staff notifying such persons should be prepared to respond to basic questions concerning the patient's condition and the process of determining brain death.

Reasonable Accommodation

Hospitals must establish written procedures for the reasonable accommodation of the individual's religious or moral objections to use of the brain death standard to determine death when such an objection has been expressed by the patient prior to the loss of decision-making capacity, or by the next of kin or other person closest to the individual. Policies may include

specific accommodations, such as the continuation of artificial respiration under certain circumstances, as well as guidance on limits to accommodation. Policies may also provide guidance on the use of other resources, such as clergy members, ethics committees, counselors and conflict mediators to address objections or concerns. Since objections to the brain death standard based solely upon psychological denial that death has occurred or on an alleged inadequacy of the brain death determination are not based upon the individual's moral or religious beliefs, "reasonable accommodation" is not required in such circumstances. However, hospital staff should demonstrate sensitivity to these concerns and consider using similar resources to help family members accept the determination and fact of death.

Brain Death Determination Policies

Hospitals are required to establish written policies that specify the process for determining brain death, including a description of examinations and tests to be employed, and who can perform the exam and make the determination. The following pages provide guidance to clinicians and facilities making such determinations. The Department recommends hospitals use these guidelines in developing their own written policies while tailoring confirmatory testing to the specific resources available in their facility.

Responsibilities of Physicians Determining Brain Death

The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including each of two assessments of brain stem reflexes and a single apnea test, is conclusively performed. In the absence of either complete clinical findings consistent with brain death, or confirmatory tests demonstrating brain death, brain death cannot be diagnosed and certified. These guidelines apply to patients one year of age or older. *Please see Appendix for the determination of brain death in children less than 1 year old.* The steps for determining brain death are summarized below, and explained in more detail in the following pages:

1. **Evaluate the irreversibility and potential causes of coma;**
2. **Initiate the hospital policy for notifying the next of kin;**
3. **Conduct and document the first clinical assessment of brain stem reflexes;**
4. **Observe the individual during a defined waiting period for any clinical inconsistencies with the diagnosis of brain death;**
5. **Conduct and document the second clinical assessment of brain stem reflexes;**
6. **Perform and document the apnea test;**
7. **Perform confirmatory testing, if indicated;**
8. **If the individual's religious or moral objection to the brain death standard is known, implement hospital policies for reasonable accommodation;**
9. **Certify brain death; and**
10. **Withdraw cardio-respiratory support in accordance with hospital policies, including those for organ donation.**

Step 1: **Evaluation of Coma**

The determination of brain death requires the identification of the proximate cause and irreversibility of coma. Severe head injury, hypertensive intracerebral hemorrhage, aneurysmal subarachnoid hemorrhage, hypoxic-ischemic brain insults and fulminant hepatic failure are potential causes of irreversible loss of brain function. The physician should assess the extent and potential reversibility of any damage, and also rule out confounding factors such as drug intoxication, neuromuscular blockade, hypothermia, or other metabolic abnormalities that cause coma but are potentially reversible.

The evaluation of a potentially irreversible coma should include, as may be appropriate to the particular case:

- Clinical or neuro-imaging evidence of an acute CNS catastrophe that is compatible with the clinical diagnosis of brain death;

- Exclusion of complicating medical conditions that may confound clinical assessment (e.g., no severe electrolyte, acid-base, or endocrine disturbance);

- Lack of significant hypothermia or hypotension:

    - Core temperature:
        - (age ≥18 years) ≥ 32° C (89.6°F)
        - (age ≥ 1 year < 18 years) Consider age specific norms
        - (age < 1 year) See appendix

    - Systolic blood pressure:
        - (age ≥ 18 years) ≥ 90 mm Hg
        - (age ≥ 1 year < 18 years) Consider age specific norms
        - (age < 1 year) See appendix

- Exclusion of drug intoxication or poisoning.

If intoxicants such as barbiturates are present, levels need not be zero, but should be in a range that would not normally be expected to interfere significantly with consciousness. Since it is impossible to stipulate specific levels for every drug, experienced clinical judgment is necessary. A cerebral blood flow study that demonstrates absent intracranial blood flow is consistent with the diagnosis of brain death even in the presence of CNS depressants. If neuromuscular junction blocking agents have been used, there should be evidence of neuromuscular transmission, i.e. deep tendon reflexes, other clinical muscle function, or responses to electrical stimulation of motor nerves, before beginning the determination of brain death.

Step 2: **Notify Next of Kin**

The facility must make diligent efforts to notify the person closest to the patient that the process for determining brain death is underway. Consent need not be obtained but requests for reasonable accommodation based on religious or moral objections should be noted and referred to appropriate hospital staff. Where family members object to invasive confirmatory tests, physicians should rely on the guidance of hospital counsel and the ethics committee.

Step 3: **Initial Clinical Assessment of Brain Stem Reflexes**

The brain death determination requires two clinical assessments of brain function, separated by a period of hours. The apnea test is typically performed after the second evaluation of brainstem reflexes.

The three essential findings in brain death are coma or unresponsiveness, absence of brainstem reflexes, and apnea. The determination of brain death verifies these findings by the following clinical indications:

- **Coma or unresponsiveness:** no cerebral motor response to pain in all extremities (nail-bed pressure) and supraorbital pressure

- **Absence of brainstem reflexes**
  - Pupils
    - No response to bright light
    - Size: midposition (4 mm) to dilated (9 mm)

  - Ocular movement
    - No oculocephalic reflex (testing only when no fracture or instability of the cervical spine or skull base is apparent)
    - No deviation of the eyes to irrigation in each ear with 50 ml of cold water (tympanic membranes intact; allow 1 minute after injection and at least 5 minutes between testing on each side)

  - Facial sensation and facial motor response
    - No corneal reflex
    - No jaw reflex (optional)
    - No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint

  - Pharyngeal and tracheal reflexes
    - No response after stimulation of the posterior pharynx
    - No cough response to tracheobronchial suctioning

Confounding Factors: The following conditions may interfere with the clinical diagnosis of brain death, so that the diagnosis cannot be made with certainty on clinical grounds alone. In such instances, confirmatory tests are recommended.

- Severe facial or cervical spine trauma
- Preexisting pupillary abnormalities
- Toxic levels of any sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptic drugs, chemotherapeutic agents, or neuromuscular blocking agents
- Sleep apnea or severe pulmonary disease resulting in chronic retention of CO_2

Clinical observations compatible with the diagnosis of brain death: The following manifestations are occasionally seen and should not be misinterpreted as evidence for brainstem function:

- Spontaneous movements of limbs other than pathologic flexion or extension response
- Respiratory-like movements (shoulder elevation and adduction, back arching, intercostal expansion without significant tidal volumes)
- Sweating, flushing, tachycardia
- Normal blood pressure without pharmacologic support or sudden increases in blood pressure
- Absence of diabetes insipidus
- Deep tendon reflexes; superficial abdominal reflexes; triple flexion response
- Babinski reflex

Step 4: **Interval Observation Period**

After the first clinical exam, the patient should be observed for a defined period of time for clinical manifestations that are inconsistent with the diagnosis of brain death. Most experts agree that a 6 hour observation period is sufficient and reasonable in adults and children over the age of 1 year. Longer intervals are advisable in young children. *Please see appendix for the determination of brain death in children less than 1 year old*

When a confirmatory test confirms the diagnosis of brain death, the interval between clinical assessments can be shortened to 2 hours. If any part of the clinical determination including the apnea test cannot be completed, one of the confirmatory tests is required and the interval may be shortened to 2 hours.

Step 5: **Repeat Clinical Assessment of Brain Stem Reflexes**

The exam as described in Step 3 above should be repeated in full and documented. When clinical circumstances prohibit completion of any steps in the clinical examination, these should be documented.

Step 6: **Apnea Test**

Generally, the apnea test is performed after the second examination of brainstem reflexes. The apnea test need only be performed once when its results are conclusive.

Before performing the apnea test, the physician must determine that the patient meets the following conditions:

- Core temperature ≥ 36.5°C or 97.7°F
- Euvolemia. *Option:* positive fluid balance in the previous 6 hours
- Normal PCO_2. *Option:* arterial $PCO_2 \geq 40$ mm Hg
- Normal PO_2 *Option:* pre-oxygenation to arterial $PO_2 \geq 200$ mm Hg

After determining that the patient meets the prerequisites above. the physician should conduct the apnea test as follows:

- Connect a pulse oximeter and disconnect the ventilator.
- Deliver 100% O_2, 6 l/min. into the trachea. *Option:* place a cannula at the level of the carina.
- Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes).
- Measure arterial PO_2, PCO_2, and pH after approximately 8 minutes and reconnect the ventilator.
- If respiratory movements are absent and arterial PCO_2 is ≥ 60 mm Hg (*option:* 20 mm Hg increase in PCO_2 over a baseline normal PCO_2), the apnea test result is positive (i.e. it supports the diagnosis of brain death).
- If respiratory movements are observed. the apnea test result is negative (i.e. it does not support the clinical diagnosis of brain death).
- Connect the ventilator if, during testing, the systolic blood pressure becomes < 90 mm Hg (or below age appropriate thresholds in children less than 18 years of age) or the pulse oximeter indicates significant oxygen desaturation, or cardiac arrhythmias develop; immediately draw an arterial blood sample and analyze arterial blood gas. If PCO_2 is ≥ 60 mm Hg or PCO_2 increase is ≥ 20 mm Hg over baseline normal PCO_2, the apnea test result is positive (it supports the clinical diagnosis of brain death); if PCO_2 is < 60 mm Hg and PCO_2 increase is < 20 mm Hg over baseline normal PCO_2, the result is indeterminate and a confirmatory test can be considered.

Step 7: Confirmatory Testing as Indicated

When the full clinical examination, including both assessments of brain stem reflexes and the apnea test, is conclusively performed, no additional testing is required to determine brain death. In some patients, skull or cervical injuries, cardiovascular instability, or other factors may make it impossible to complete parts of the assessment safely. In such circumstances, a confirmatory test verifying brain death is necessary. These tests may also be used to reassure family members and medical staff. Based on clinical indications, confirmatory testing may sometimes precede other aspects of the determination of brain death; it may also occur in the interval between assessments of brainstem reflexes or after.

Documentation should indicate which parts of the clinical examination could not be completed safely, along with the reason. Even when confirmatory testing is consistent with brain death, as when absent cerebral blood flow is documented, brain death protocols still require two assessments of brain stem reflexes.

Any of the suggested tests may produce similar results in patients with catastrophic brain damage who do not (yet) fulfill the clinical criteria of brain death. The diagnosis of brain death rests on the clear determination of the cause of coma, the elimination of potentially confounding factors, the results of the clinical exams and those of confirmatory tests as indicated.

The choice of a confirmatory test is dictated in large part by practical considerations, i.e. availability, advantages and disadvantages. Currently available confirmatory tests are listed below, in alphabetical order, along with the findings consistent with brain death and complicating factors.

- Angiography (conventional, computerized tomographic, magnetic resonance, and radionuclide): Brain death confirmed by demonstrating the absence of intracerebral filling at the level of the carotid bifurcation or Circle of Willis. The external carotid circulation is patent, and filling of the superior sagittal sinus may be delayed.
    - Radionuclide angiography (CRAG) does not adequately image vasculature of the posterior fossa.
    - MRI angiography can be quite challenging in an ICU patient because of magnet incompatibility with lines, ventilator tubing and other hardware.
    - Cerebral arteriography: This test is often difficult to perform in a critically ill, unstable patient.

- Electroencephalography: Brain death confirmed by documenting the absence of electrical activity during at least 30 minutes of recording that adheres to the minimal technical criteria for EEG recording in suspected brain death as adopted by the American Electroencephalographic Society, including 16-channel EEG instruments. (See reference 1 below.)
    - The ICU setting may result in false readings due to electronic background noise creating innumerable artifacts.

- Nuclear brain scanning: Brain death confirmed by absence of uptake of isotope in brain parenchyma and/or vasculature, depending on isotope and technique used. ("hollow skull phenomenon"). (See reference 2 below.)

- Somatosensory evoked potentials: Brain death confirmed by bilateral absence of N20-P22 response with median nerve stimulation. The recordings should adhere to the minimal technical criteria for somatosensory evoked potential recording in suspected brain death as adopted by the American Electroencephalographic Society.

- Transcranial doppler ultrasonography: Brain death confirmed by small systolic peaks in early systole without diastolic flow, or reverberating flow, indicating very high vascular resistance associated with greatly increased intracranial pressure.
    - Since as many as 10% of patients may not have temporal insonation windows because of skull thickness, the initial absence of Doppler signals cannot be interpreted as consistent with brain death.

Step 8: **Reasonable Accommodation**

When an objection to brain death based on religious or moral grounds is raised, physicians should follow hospital policy for providing reasonable accommodation.

Step 9: **Certification of Brain Death**

Brain death can be certified by a single physician privileged to make brain death determinations. However, before a patient can become an organ donor, New York State law requires that the time of brain death must be certified by the physician who attends the donor at his death and one other physician, neither of whom shall participate in the process of transplantation. This requirement ensures that all evaluations meet accepted medical standards, and that all participants can have confidence that brain death determination has not been influenced by extraneous factors, including the needs of potential organ recipients.

When two physicians are required to certify the time of death, i.e., when organ donation is planned, both physicians should affirm that the clinical evaluation meets accepted medical standards, and that the data fully support the determination of brain death. Generally, both physicians should observe the patient, review the medical record, and note whether any additional information is required to make a definitive determination. Neither physician should certify brain death unless all aspects of the determination have been completed.

Medical Record Documentation: All phases of the determination of brain death should be documented in the medical record; a sample checklist and certification notice are appended at the end of this guidance. The medical record must indicate:

- Etiology and irreversibility of coma/unresponsiveness
- Absence of motor response to pain
- Absence of brainstem reflexes during two separate exams, separated by hours
- Absence of respiration with $PCO_2 \geq 60$ mm Hg
- Justification for, and result of, confirmatory tests if used

Step 10: **Withdraw cardio-respiratory support in accordance with hospital policies, including those for organ donation**

When a patient is certified as brain dead and the ventilator is to be disconnected, the family should be treated with sensitivity and respect. If family members wish, they may be offered the opportunity to attend while the ventilator is disconnected. However, family members should be prepared for the possibly disturbing clinical activity that they may witness. When organ donation is contemplated, ventilatory support will conclude in the operating room and family attendance is not appropriate.

Appendix: Determination of Brain Death In Children Less Than One Year of Age

1. General Policy Statement.

The brains of infants and young children have increased resistance to damage and may recover substantial functions even after exhibiting unresponsiveness on neurological examination for longer periods as compared to adults. When applying neurological criteria to determine death in children younger than one year. longer observation periods are required.

2. The patient must not be significantly hypothermic or hypotensive for age.

3. Observation Periods According to Age.

The recommended observation period depends on the age of the patient and the laboratory tests utilized. Ages listed assume the child was born at full term. Between the ages of 2 months and 1 year, an interval of at least 24 hours should be used. Between the ages of 7 days and 2 months, the minimum interval should be 48 hours.

- Reliable criteria have not been established for the determination of brain death in children less than 7 days old.
- Seven days to two months: Two examinations and electroencephalograms (EEGs) should be separated by at least 48 hours.
- Two months to one year: Two examinations and EEGs should be separated by at least 24 hours. A repeat examination and EEG are not necessary if a concomitant radionuclide (CRAG) or other angiographic study demonstrates no visualization of cerebral arteries.

References for Voluntary Consensus Guidelines for Determining Brain Death:

1. American Electroencephalographic Society. Guideline three: minimum technical standards for EEG recording in suspected cerebral death. J Clin Neurophysiol. 1994 Jan; 11(1): 10-13.

2. Donohue KJ. Frey KA, Gerbaudo VH. Nagel JS. Shulkin B. Society of Nuclear Medicine Procedure Guideline for Brain Death Scintigraphy. J Nucl Med. 2003 May; 44(5): 846-51.

3. Quality Standards Subcommittee of the American Academy of Neurology.
Practice parameters for determining brain death in adults (summary statement). Neurology. 1995 May; 45(5): 1012-4.

4. Task Force for the determination of brain death in children. Guidelines for the determination of brain death in children. Neurology 1987: 37: 1077-1078.

5. Wijdicks EF. Determining brain death in adults. Neurology. 1995 May: 45(5): 1003-11.

6. Wijdicks EF. The diagnosis of brain death. N Engl J Med. 2001 Apr 19: 344(16): 1215-21.

Brain Death Checklist

Patient's Name: ______________________________

	Examination #1	Examination #2
THE CAUSE OF BRAIN DEATH IS KNOWN AND IRREVERSIBLE		
Exclusion of complicating medical conditions that may confound the clinical assessment of brain death.	**Date & Time:** **Physician Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Physician Initials:** ☐ Yes ☐ No **Explanation:**
Is core body temperature ≥ 32° C (89.6°F)?	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**
If CNS depressants or neuromuscular blockade present, are concentrations sufficiently low that they will not interfere with the assessment for brain death?	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**
Is systolic blood pressure ≥ 90mm Hg ?	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**
In children <18 years of age, are core body temperature and systolic blood pressure in an acceptable range for age?	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**
The relevant family member or appropriate party has been notified of the intention to initiate the determination of brain death.	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**

DETERMINATION OF UNRESPONSIVENESS		
Absence of supraspinal motor response to pain in all extremities (nail bed pressure and supraorbital pressure)	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:
ABSENCE OF BRAINSTEM REFLEXES		
No pupillary response to light Size: midposition (4mm) to dilated (9mm)	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**	**Date & Time:** **Initials:** ☐ Yes ☐ No **Explanation:**
No oculocephalic reflex (Note: to be tested only when fracture or instability of the cervical spine and skull base have been excluded.)	Date & Time: Initials: ☐ Yes ☐ No **Explanation:**	Date & Time: Initials: ☐ Yes ☐ No **Explanation:**
No deviation of the eyes to irrigation of each ear with 50 ml of cold water. (Note: the tympanic membrane must be intact.)	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:
No corneal reflex	Date & Time: Initials: ☐ Yes ☐ No **Explanation:**	Date & Time: Initials: ☐ Yes ☐ No **Explanation:**
No jaw reflex (optional)	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:	**Date & Time:** **Initials:** ☐ Yes ☐ No Explanation:

No response to stimulation of the posterior pharynx and/or no cough response to tracheobronchial suctioning.	Date & Time: Initials: ☐ Yes ☐ No Explanation:	Date & Time: Initials: ☐ Yes ☐ No Explanation:

Apnea Testing Prerequisites:

Core temperature ≥ 36.5°C or 97.7°F ☐ **Yes**

Euvolemia. Option : positive fluid balance in the previous 6 hours ☐ **Yes**

Normal PCO_2. Option: arterial $PCO_2 \geq$ 40 mm Hg ☐ **Yes**

Normal PO_2 Option: pre-oxygenation to obtain arterial $PO_2 > 200$mm Hg if possible. ☐ **Yes**

Apnea Testing Process:

Deliver 100% oxygen via the ventilator for 10 minutes prior to starting the test. ☐ **Complete**

Draw a baseline arterial blood gas. ☐ **Complete**

Connect a pulse oximeter and disconnect the ventilator ☐ **Complete**

Deliver 100% oxygen into the trachea via cannula in the ET tube, at 6 l/minute. ☐ **Complete**

If tolerated, leave the patient off the ventilator for 8-10 minutes. ☐ **Complete**

Observe the patient carefully for respiratory movements. ☐ **Complete**

Draw another blood gas at the end of the 8-10 minutes and reconnect the ventilator. ☐ **Complete**

Apnea Testing Documentation:

Length of apnea test ______________

PCO_2 at end of test

Did patient breath during the test? ☐ Yes ☐ No Comments:

If the $PCO_2 \geq 60$mm Hg or the PCO_2 increase was at least 20 mm Hg over the initial normal baseline PCO2, the test is positive and supports the diagnosis of brain death. ☐ **Confirms Brain Death**

If the patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of significant arrhythmias, the test is uninterpretable and either should be repeated, or supplanted with a confirmatory test. If the pCO2 does not exceed 60 mmHg after 10 minutes of apnea, or does not increase 20 mm from normal baseline, the test does not confirm the diagnosis of brain death. ☐ **Does Not Confirm Brain Death**

If Confirmatory Testing Is Performed

Which test was performed?______________________________

What was the interpretation of the test?___________________________

Documentation of Brain Death

A physician shall certify a patient as brain dead when the patient fulfills the criteria described in these guidelines. Before a patient can be an organ donor, a second physician certification is required.

Physician Certification:

Print Name________________________________ Date/Time of death_____________________

Signature____

Second Physician Certification (Necessary for organ donation):

Print Name________________________________ Date/Time of death: ___________________

Signature____

New York State Department of Health

Brain Death Guidelines Review Panel

Participants

Tia Powell, MD (Chair)
Executive Director
New York State Task Force on Life and the Law

Elaine Berg, MPA
President and CEO
New York Organ Donor Network

Gregory Castiglia, MD
Neurosurgeon
Buffalo Neurosurgery Group

Julius Cheng, MD, MPH
Medical Director, Burn-Trauma ICU
University of Rochester Medical Center

Joseph Jack Fins, MD, FACP
Chief, Division of Medical Ethics
Cornell University

John Halperin, MD
Professor of Neurology,
NYU School of Medicine
Attending Neurologist,
North Shore University Hospital

Jeffrey Oppenheim, MD
Neurosurgeon
Hudson Valley Neurosurgical Associates

Margaret Paroski, MD
Interim Vice President of Health Affairs
University of Buffalo

Wouter J. Rietsema, MD
Vice President of Medical Affairs
CVPH Medical Center

Stanley Rothman, MD
Associate Professor of Pediatric Neurology
Mount Sinai School of Medicine

Maryann Sharpe-Casesse, BSN, MSN, CPTC
Chair, Ethical Practice & Human Rights Council
New York State Nurses Association

Mark Simon
Chief Executive Officer
Upstate New York Transplant Services, Inc.

Raymond Walsh, MD
Pediatric Intensive Care Specialist
Albany Medical Center

James Zisfein, MD
Chief of Neurology
Lincoln Medical & Mental Health Center

Judy Doesschate, JD
Division of Legal Affairs

Lisa McMurdo, RN
Division of Healthcare Standards and Surveillance

1. DATE ISSUED: 09/10/2007

2. PROGRAM CFDA: 93.134

3. SUPERCEDES AWARD NOTICE dated:
except that any additions or restrictions previously imposed remain in effect unless specifically rescinded.

4a. AWARD NO.: 1 R38OT08761-01-00

4b. GRANT NO.: R38OT08761

5. FORMER GRANT NO.:

6. PROJECT PERIOD:
FROM: 09/01/2007 THROUGH: 08/31/2010

7. BUDGET PERIOD:
FROM: 09/01/2007 THROUGH: 08/31/2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION

HRSA

NOTICE OF GRANT AWARD
AUTHORIZATION (Legislation/Regulation)
Public Health Service Act, Section 371 (a) (3) 42, U.S.C. 273 (a) (3) as Amended
Public Health Service Act, Section 377A,as amended, 42 U.S.C. Section 274f-1

8. TITLE OF PROJECT (OR PROGRAM): Clinical Interventions to Increase Organ Procurement

9. GRANTEE NAME AND ADDRESS:
NEW YORK CITY HEALTH & HOSPITALS CORPORATION
125 WORTH STREET
NEW YORK, NY 10013-4006

10. DIRECTOR: (PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR)
Lewis Goldfrank
NEW YORK CITY HEALTH & HOSPITALS CORPORATION
Emergency Medicine
462 First Avenue
New York, NY 10016-9196

11. APPROVED BUDGET: (Excludes Direct Assistance)
[X] Grant Funds Only
[ ] Total project costs including grant funds and all other financial participation

Item	Amount
a. Salaries and Wages:	$ 55,920.00
b. Fringe Benefits:	$ 17,354.00
c. Total Personnel Costs:	$ 73,274.00
d. Consultant Costs:	$ 0.00
e. Equipment:	$ 19,000.00
f. Supplies:	$ 0.00
g. Travel:	$ 2,500.00
h. Construction/Alteration and Renovation:	$ 0.00
i. Other:	$ 0.00
j. Consortium/Contractual Costs:	$ 362,117.00
k. Trainee Related Expenses:	$ 0.00
l. Trainee Stipends:	$ 0.00
m. Trainee Tuition and Fees:	$ 0.00
n. Trainee Travel:	$ 0.00
o. TOTAL DIRECT COSTS:	**$ 456,891.00**
p. INDIRECT COSTS: (Rate: % of S&W/TADC)	**$ 13,580.00**
q. TOTAL APPROVED BUDGET:	**$ 470,471.00**
i. Less Non-Federal Resources:	$ 0.00
ii. Federal Share:	$ 470,471.00

12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE

Item	Amount
a. Authorized Financial Assistance This Period	**$ 470,471.00**
b. Less Unobligated Balance from Prior Budget Periods	
i. Additional Authority	$ 0.00
ii. Offset	$ 0.00
c. Unawarded Balance of Current Year's Funds	$ 0.00
d. Less Cumulative Prior Award(s) This Budget Period	$ 0.00
e. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION	**$ 470,471.00**

13. RECOMMENDED FUTURE SUPPORT: (Subject to the availability of funds and satisfactory progress of project)

YEAR	TOTAL COSTS
02	$ 626,740.00
03	$ 520,565.00

14. APPROVED DIRECT ASSISTANCE BUDGET: (In lieu of cash)

Item	Amount
a. Amount of Direct Assistance	$ 0.00
b. Less Unawarded Balance of Current Year's Funds	$ 0.00
c. Less Cumulative Prior Awards(s) This Budget Period	$ 0.00
d. AMOUNT OF DIRECT ASSISTANCE THIS ACTION	**$ 0.00**

15. PROGRAM INCOME SUBJECT TO 45 CFR Part 74.24 OR 45 CFR 92.25 SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES:
A=Addition B=Deduction C=Cost Sharing or Matching D=Other **[A]**
Estimated Program Income: $ 0.00

16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY HRSA, IS ON THE ABOVE TITLED PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:
a. The grant program legislation cited above. b. The grant program regulation cited above. c. This award notice including terms and conditions, if any, noted below under REMARKS. d. 45 CFR Part 74 or 45 CFR Part 92 as applicable. In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall prevail. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system.

REMARKS: (Other Terms and Conditions Attached **[X] Yes [ ] No**)

Electronically signed by John Gallicchio, Grants Management Officer on: 09/10/2007

17. OBJ. CLASS: 41.41 **18. CRS-EIN:** 1132655001A1 **19. FUTURE RECOMMENDED FUNDING:**

FY-CAN	CFDA	DOCUMENT NO.	AMT. FIN. ASST.	AMT. DIR. ASST.	SUBPROGRAM CODE
07-3880702	93.134	R38OT08761A0	$ 470,471.00	$ 0.00	N/A