

Healthcare Systems Bureau
Clinical Interventions for Increasing Organ Procurement Grant Program (CIOP)
Application Number 44020

New York City Health and Hospitals Corporation
Conditions of Award

1. Please describe in more detail the role of the transplant surgeon and how conflicts of interest, either real or perceived will be avoided.
2. Please plan and describe what methods will be used for achieving buy-in from the public and public officials in a timely manner that allows for completion of the project
3. Address the Object Review Panels' concern that costs associated with public relations expenses and a campaign will be extensive. Describe what methods you will utilize to remain within the proposed budget.
4. Please describe in greater detail the community notification process without direct informed consent, including how this will be implemented and evaluated.
5. The Objective Review Panel felt that the timeline was "markedly" unrealistic to meet the objective(s). Please elaborate on how you will meet the objectives within the given timeline or how you might revise the activities and/or timeline to meet the objectives within the timeframe allotted.
6. Address the Object Review Panel's concern that operating the Rapid Organ Response Ambulance one shift per day will decrease already small numbers by one-third.
7. Please provide specific metrics regarding the cooling process.
8. Discuss in greater detail how the PI will handle current duties and ensure the success of this project.
9. Discuss in greater detail how the PI and co-investigators will work together to ensure this projects success. What methods will be used to remain on task, how will the PI and co-investigators remain in action?
10. Discuss personnel costs as related to percent of effort taking into consideration actual time able to be spent on this project.

From: Goldfrank, Lewis [mailto:Lewis.Goldfrank@nyumc.org]
Sent: Friday, August 10, 2007 3:18 PM
To: Kozlovsky, Bernard (HRSA)
Cc: Barney, Brad (HRSA)
Subject: Responses to Questions Concerning CIOP Application #44020

It was a pleasure talking with you this morning. I appreciated your assistance in hopefully resolving completely your queries. Should there be any further difficulty following the attached responses, I will respond immediately. We look forward with great enthusiasm to the possibility of the funding of our proposal.

Sincerely,

Lewis Goldfrank

Responses to Questions concerning CIOP application # 44020

Question 1

Please describe in greater detail the community notification process without direct informed consent, including how this will be implemented and evaluated.

According to New York State law, informed consent is only required for the donor recipient, not the deceased. As a matter of sensitivity, the Organ Donor Network involves the family in the process of determining whether the deceased would have wanted to donate organs, if not explicitly stated prior to death.

In accordance with the IOM report Organ Donation: Opportunities for Action 2006 and a recent report issued by the Department of Health of the State of New York, this pilot will enable the Rapid Organ Recovery Ambulance team to "presume consent" to transport the deceased and to maintain the organs until such time as the family can be contacted to ascertain the wishes of the deceased or proof of preexisting entry in the organ donation registry can be determined. This is referred to as "preserving the right to donate organs."

The community "notification" process is a community education effort to raise awareness about the issues and to generate support for the pilot so as to manage religious, ethical and political concerns in a City with over 160 distinct cultures. This will be accomplished by conducting focus groups with various stakeholders. The data culled from the focus groups will help craft the marketing message for the project. A professional market research firm will be used to collect and analyze data throughout the process to inform the team in the development of messages and educational materials that are most acceptable to the various stakeholders. A key component of the strategy is to develop an ethical white paper, a task to be led by one of our investigators Nancy Dubler, LLB a well-known medical ethicist who also participated in the most recent IOM Report.

Question 2

Address the concern that operating the Rapid Organ Response Ambulance one shift per day will decrease already small numbers of potential UDCD donors by one-third.

Through discussions with various City officials, a key concern was the cost of running the Rapid Organ Recovery Ambulance 7 days per week. It was felt that given the limited resources available at this time, the most cost-effective strategy would be to run a pilot on one shift per day, 7 days per week for 2 years. This would enable the study to demonstrate a societal benefit and to gain support for additional funding for a full-Citywide effort. While the numbers of potential donors are modest, they dramatically increase the donations that result following cardiac death. In addition, they are adequate for us to achieve our primary analysis and three secondary analyses. Also, it was felt that conducting a pilot from midnight to 8am would permit the rapid transport of potential donors, given the significantly reduced traffic congestion at that time.

Question 3

Discuss personnel costs as related to percent effort taking into consideration actual time to be spent on this project. Please take into consideration the other responsibilities of the primaries, the short timeline for completion of the project and work flow.

The principal investigator Lewis Goldfrank, MD and the co-principal investigator Eric Grossman, MD are committed to this effort. Both physicians began their interest in organ donation many years ago, and both recognize that the future of organ donation depends on increasing the pool of available organs through donation after cardiac death. As leaders in their organizations, both individuals have the ability to mobilize additional in-kind resources. For example, Dr. Goldfrank recently hired Stephen Wall, MD a current AHRQ recipient who is conducting related research on attitudes about organ donations among different ethnic populations in New York City. Dr. Goldfrank will be utilizing the work of all related research in his department to inspire our hospital personnel and lead to the optimization of essential resources for the HRSA grant should it be awarded to our institutions.

Additionally, the Department of Emergency Medicine, recently hired its first Vice Chairman. This addition will permit Dr. Goldfrank to be relieved of many administrative tasks permitting him to focus on this research and other public health and emergency healthcare issues.

Lewis R. Goldfrank, MD
Professor and Chair, Emergency Medicine
New York University School of Medicine
Director, Emergency Medicine
Bellevue Hospital/NYU Hospitals/
VA Medical Center
Medical, New York City Poison Center

Telephone: 212.562.3346
Fax: 212.562.3001
Email: goldfl03@med.nyu.edu
Website: <http://www.med.nyu.edu/emergency>

DRAFT

Healthcare Systems Bureau

8/17/07

TO: Associate Administrator
FROM: Director, Division of Transplantation
SUBJECT: FY 2007 Extramural Grant Program: Social and Behavioral Interventions to Increase Organ and Tissue Donation—ACTION

ISSUE

Fourteen applications were submitted for the FY 2007 Extramural Grant Program: Social and Behavioral Interventions to Increase Organ and Tissue Donation. One application was deemed ineligible. An objective review committee (ORC) reviewed the remaining thirteen applications on May 15-17, 2007. All applications reviewed were scored for merit using a scale of 10-100.

DISCUSSION

Based upon the recommendations of the ORC and the availability of funds, the Division of Transplantation recommends funding five (5) applications from this grant cycle. Attached is a chart of the recommended grants for funding. Any organization that has not submitted 100 percent of the data required by the policies of the Organ Procurement and Transplantation Network (OPTN) will not receive grant funding.

With Hold

The CAN number 7-3880701 and Allowance number 7-97003 will be used for this grant cycle.

RECOMMENDATION

I recommend that you approve the attached grant list.

DECISION

I approve the attached grant list.

Concur: _____ Non-Concur: _____ Date: _____

James F. Burdick, M.D.

Attachment

Prep by:HRSA/HSB/DoT/VWALKER:H:/Shared/DT/General/Controlled/Funding Memo/Social &

DRAFT

**Healthcare Systems Bureau
Clinical Interventions for Increasing Organ Procurement Grant Program (CIOP)
Application Number 44020**

**New York City Health and Hospitals Corporation
Conditions of Award**

1. Please describe in more detail the role of the transplant surgeon and how conflicts of interest, either real or perceived will be avoided.
2. Please plan and describe what methods will be used for achieving buy-in from the public and public officials in a timely manner that allows for completion of the project
3. Address the Object Review Panels' concern that costs associated with public relations expenses and a campaign will be extensive. Describe what methods you will utilize to remain within the proposed budget.
4. Please describe in greater detail the community notification process without direct informed consent, including how this will be implemented and evaluated.
5. The Objective Review Panel felt that the timeline was "markedly" unrealistic to meet the objective(s). Please elaborate on how you will meet the objectives within the given timeline or how you might revise the activities and/or timeline to meet the objectives within the timeframe allotted.
6. Address the Object Review Panel's concern that operating the Rapid Organ Response Ambulance one shift per day will decrease already small numbers by one-third.
7. Please provide specific metrics regarding the cooling process.
8. Discuss in greater detail how the PI will handle current duties and ensure the success of this project.
9. Discuss in greater detail how the PI and co-investigators will work together to ensure this projects success. What methods will be used to remain on task, how will the PI and co-investigators remain in action?
10. Discuss personnel costs as related to percent of effort taking into consideration actual time able to be spent on this project.

Clinical Interventions to Increase Organ Procurement Grant Program FY 2007 Competing Awards

Application #	Grant #	Grantee	City/State	Inception Year	Funding Request
44014		University of Pittsburgh	Pittsburgh, PA	FY 2007	286,974.00
44020		New York City Health and Hospitals Corp.	New York, NY	FY 2007	470,471.00
Total					757,445.00

DRAFT

Kozlovsky, Bernard (HRSA)

From: Goldfrank, Lewis [Lewis.Goldfrank@nyumc.org]
Sent: Thursday, August 09, 2007 5:51 PM
To: Kozlovsky, Bernard (HRSA)
Cc: Barney, Brad (HRSA)
Subject: Responses to Questions Concerning CIOP Application #44020

It was a pleasure talking with you this morning. I appreciated your assistance in hopefully resolving completely your queries. Should there be any further difficulty following the attached responses, I will respond immediately. We look forward with great enthusiasm to the possibility of the funding of our proposal.

Sincerely,

Lewis Goldfrank

Responses to Questions concerning CIOP application #44020

Question 1

Please describe in greater detail the community notification process without direct informed consent, including how this will be implemented and evaluated.

According to New York State law, informed consent is only required for the donor recipient, not the deceased. As a matter of sensitivity, the Organ Donor Network involves the family in the process of determining whether the deceased would have wanted to donate organs, if not explicitly stated prior to death.

In accordance with the IOM report Organ Donation: Opportunities for Action 2006 and a recent report issued by the Department of Health of the State of New York, this pilot will enable the Rapid Organ Recovery Ambulance team to "presume consent" to transport the deceased and to maintain the organs until such time as the family can be contacted to ascertain the wishes of the deceased or proof of preexisting entry in the organ donation registry can be determined. This is referred to as "preserving the right to donate organs."

The community "notification" process is a community education effort to raise awareness about the issues and to generate support for the pilot so as to manage religious, ethical and political concerns in a City with over 160 distinct cultures. This will be accomplished by conducting focus groups with various stakeholders. The data culled from the focus groups will help craft the marketing message for the project. A professional market research firm will be used to collect and analyze data throughout the process to inform the team in the development of messages and educational materials that are most acceptable to the various stakeholders. A key component of the strategy is to develop an ethical white paper, a task to be led by one of our investigators Nancy Dubler, LLB a well-known medical ethicist who also participated in the most recent IOM Report.

Question 2

Address the concern that operating the Rapid Organ Response Ambulance one shift per day will decrease already small numbers of potential UDCD donors by one-third.

Through discussions with various City officials, a key concern was the cost of running the Rapid Organ Recovery

From: Goldfrank, Lewis [mailto:Lewis.Goldfrank@nyumc.org]
Sent: Friday, August 10, 2007 3:18 PM
To: Kozlovsky, Bernard (HRSA)
Cc: Barney, Brad (HRSA)
Subject: Responses to Questions Concerning CIOP Application #44020

Lewis

It was a pleasure talking with you this morning. I appreciated your assistance in hopefully resolving completely your queries. Should there be any further difficulty following the attached responses, I will respond immediately. We look forward with great enthusiasm to the possibility of the funding of our proposal.

Sincerely,

Lewis Goldfrank

Responses to Questions concerning CIOP application #44020

Question 1

Please describe in greater detail the community notification process without direct informed consent, including how this will be implemented and evaluated.

According to New York State law, informed consent is only required for the donor recipient, not the deceased. As a matter of sensitivity, the Organ Donor Network involves the family in the process of determining whether the deceased would have wanted to donate organs, if not explicitly stated prior to death.

In accordance with the IOM report Organ Donation: Opportunities for Action 2006 and a recent report issued by the Department of Health of the State of New York, this pilot will enable the Rapid Organ Recovery Ambulance team to "presume consent" to transport the deceased and to maintain the organs until such time as the family can be contacted to ascertain the wishes of the deceased or proof of preexisting entry in the organ donation registry can be determined. This is referred to as "preserving the right to donate organs."

The community "notification" process is a community education effort to raise awareness about the issues and to generate support for the pilot so as to manage religious, ethical and political concerns in a City with over 160 distinct cultures. This will be accomplished by conducting focus groups with various stakeholders. The data culled from the focus groups will help craft the marketing message for the project. A professional market research firm will be used to collect and analyze data throughout the process to inform the team in the development of messages and educational materials that are most acceptable to the various stakeholders. A key component of the strategy is to develop an ethical white paper, a task to be led by one of our investigators Nancy Dubler, LLB a well-known medical ethicist who also participated in the most recent IOM Report.

Question 2

Address the concern that operating the Rapid Organ Response Ambulance one shift per day will decrease already small numbers of potential UDCD donors by one-third.

Through discussions with various City officials, a key concern was the cost of running the Rapid Organ Recovery Ambulance 7 days per week. It was felt that given the limited resources available at this time, the most cost-effective strategy would be to run a pilot on one shift per day, 7 days per week for 2 years. This would enable the study to demonstrate a societal benefit and to gain support for additional funding for a full-Citywide effort. While the numbers of potential donors are modest, they dramatically increase the donations that result following cardiac death. In addition, they are adequate for us to achieve our primary analysis and three secondary analyses. Also, it was felt that conducting a pilot from midnight to 8am would permit the rapid transport of potential donors, given the significantly reduced traffic congestion at that time.

DRAFT

Question 3

Discuss personnel costs as related to percent effort taking into consideration actual time to be spent on this project. Please take into consideration the other responsibilities of the primaries, the short timeline for completion of the project and work flow.

The principal investigator Lewis Goldfrank, MD and the co-principal investigator Eric Grossman, MD are committed to this effort. Both physicians began their interest in organ donation many years ago, and both recognize that the future of organ donation depends on increasing the pool of available organs through donation after cardiac death. As leaders in their organizations, both individuals have the ability to mobilize additional in-kind resources. For example, Dr. Goldfrank recently hired Stephen Wall, MD a current AHRQ recipient who is conducting related-research on attitudes about organ donations among different ethnic populations in New York City. Dr. Goldfrank will be utilizing the work of all related-research in his department to inspire our hospital personnel and lead to the optimization of essential resources for the HRSA grant should it be awarded to our institutions.

Additionally, the Department of Emergency Medicine, recently hired its first Vice Chairman. This addition will permit Dr. Goldfrank to be relieved of many administrative tasks permitting him to focus on this research and other public health and emergency healthcare issues.

Lewis R. Goldfrank, MD
Professor and Chair, Emergency Medicine
New York University School of Medicine
Director, Emergency Medicine
Bellevue Hospital/NYU Hospitals/
VA Medical Center
Medical, New York City Poison Center

Telephone: 212.562.3346
Fax: 212.562.3001
Email: goldfl03@med.nyu.edu
Website: <http://www.med.nyu.edu/emergency>