

**Clinical Interventions to Increase Organ Procurement
Grant Program
Quarterly Progress Report
December 15, 2008**

1.) Identifying Information

Grantee Institution: New York City Health & Hospitals Corporation

Grant #: 1R38OT08761-01-00

Grant Title: Clinical Interventions to Increase Organ Procurement

Principal Investigator: Lewis Goldfrank, MD

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2.) Changes in research protocol since grant award or last progress report

There have been no significant changes to the research protocol as of the last communication with the HRSA program office. The protocol changes that reflect the tripartite consent procedure are described in the Challenges and Barriers section (section 5).

3.) Activities and Goals For This Reporting Period

For this interim report, we report on the progress for the IRB approval, protocol development, official and legal approvals, and community outreach efforts.

4.) Goals Completed For This Reporting Period

As of this report, we have 1) Finalized the UDCDD protocol after reviewing the data from stakeholder meetings, legal concerns, and adhering to official guidelines, 2) achieved approval to proceed from key political leaders, 3) begun community outreach town hall style meetings to achieve approval to proceed with the UDCDD program, 4) conducted market research with internet focus groups and quantitative surveys to assess appropriate messaging to obtain community support for the UDCDD program and 5) renewed IRB approval for the project.

5.) Challenges and Barriers

The main challenge in this reporting period was adapting the UDCDD program in a responsible manner that addresses recent historical events surrounding organ donation research. Recently, the notion of cardiac determination of death and the dead donor rule have fallen under scrutiny after a trial in pediatric patients showed that non-beating hearts in infants could be transplanted successfully into recipients; among the concerns was that the death proclamation occurred soon after the death determination. Failure to have a "hands-off" period that confirms

death led experts and the public to believe these cases were being allowed to die so that the organs may be recovered in lieu of caring for the potential donor. A debate ensued among ethicists and the media and government officials were concerned as well given the research was funded by HRSA. This negative perception fostered mistrust among the public as to organ donation practice in general given recent events in California, where a surgeon administered morphine to a patient for whom life support was terminated by family so that the organ donation could proceed as well as the events in Long Island, NY where a pediatric patient donor died from lymphoma, and hence transmitted the disease to 4 recipients.

These historical events challenged the basis of the presumed assent approach to the UDCDD protocol. In NYC, less than 5% of donors are on a registry of intent, and as of September 1, 2008, NY State replaced the registry of intent with a registry of consent, so that fewer than 1% of New Yorkers are in essence consented for organ donation by means of individual preauthorization. This contrasts with Pittsburgh, PA, where over 25% of citizens are consented by means of a consent registry. Our initial stakeholder and town hall meetings suggested that the public would accept an assent for organ preservation where the community after being informed would allow minimal procedures to occur on the deceased to preserve organ function while next of kin are contacted for organ preservation decisions. Nonetheless, given the recent climate surrounding the manner in which investigators may have breached ethical norms in other funded organ donation research projects, the new UDCDD protocol has a tripartite consent procedure where consent is obtained to initiate organ preservation first with automated chest compressions and maintaining of ventilation as heparin is administered to the deceased, followed by a second consent to allow percutaneous cannulation of the deceased and initiation of extra corporeal membranous oxygenation (ECMO) in the emergency department setting. The third consent is for the donation to proceed with standard next of kin protocols established by the organ donation community. This approach was approved by HRSA in documents that were counter signed by Lewis Goldfrank, the principal investigator for this project.

6.) Promising Developments

The UDCDD protocol has been approved by all NYC agencies' legal departments and is awaiting approval only from the NY State Commissioner of Health, Richard F. Daines, M.D. This year-long process has resulted in clearance to proceed with a target date of April 1, 2009. Initial market research with Internet focus groups and an online survey with a representative sample of the New York City Demographic are suggests that 75% of the population would accept the program after reading a brief description of it. During the quarter, 6 community meetings were held, and a questionnaire was distributed at the meetings to assess community reaction to the project. Preliminary data suggest that 84% of the participants at these meetings either strongly or somewhat support the project.

approval letter. The IRB application for the UDCDD pilot program is being composed and will be submitted shortly after January 1, 2009; the NYU IRB has been approached about this application and has suggested it will be an expedited process that typically lasts at most one month to receive approvals; after the NYU approval is obtained, all participating institutions that may receive the organs from this program will be approached for participation and individual center IRB approval.

10.) Description of funds used since last report

For the quarter (Sept 1, 2008 thru November 30, 2008), we expended \$23,999 all in PS, fringe and indirect costs. See attached file for details.