

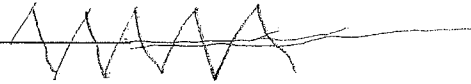
Kozlovsky, Bernard (HRSA)

From: Goldfrank, Lewis [Lewis.Goldfrank@nyumc.org]
Sent: Monday, April 14, 2008 8:51 AM
To: Kozlovsky, Bernard (HRSA)
Subject: another question

Bernard

**In the instructions to the non compete continuation guide:
Page 6- 2. content and form-line 5
Letters of commitment and support is cited.
Does this mean we need new letters of commitment?
It is not stated elsewhere.**

**Thanks for clarifying
lewis**



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**Clinical Interventions to Increase Organ Procurement
Grant Program
Quarterly Progress Report
March 25, 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

462 First Avenue, Suite 345A

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2.) Activities and Goals For This Reporting Period

For this interim report, we present the progress for the protocol derivation, key leadership approval, and general public acceptance of the Rapid Organ Recovery Ambulance (RORA) program.

3.) Goals Completed For This Reporting Period

As of this report, we have 1) achieved legal clearance from the HHC attorneys to proceed with our program development and community outreach efforts 2) finished holding our internal stakeholder meetings to achieve consensus on the appropriate, ethically sound approach to UDCD, 3) resolved legal matters surrounding the consortium contracts and, 4) drafted a plan for our public relations campaign.

4.) Challenges and Barriers

Our first challenge involved methodological differences and language associated with performing qualitative assessments of stakeholders to derive the UDCD protocol and the public relations / grass roots campaign to achieve public acceptance of the UDCD program. Originally, we thought that these methods might be combined to achieve two goals: 1) drafting the UDCD protocol and 2) achieving public support, but after consultation with our public relations staff at the NYODN and the Bellevue Hospital Center, we were strongly discouraged from such an approach. The prevailing thought was that the perception of the community would be distrust if the firm that sought public acceptance also contributed to the protocol development; akin to a pharmaceutical company promoting their new medicines through their own sponsored research (i.e. Vioxx). We resolved this challenge by the development of precise definitions for our stakeholder meetings and our focus groups to be conducted as part of our public relations market research; these definitions have been placed in a glossary so that when confusion arises during our interdisciplinary meetings, members may

The third challenge was obtaining support from the New York City Health and Hospitals Corporation senior management, and achieving support to initiate stakeholder meetings for protocol development. With aggressive lobbying efforts headed by Dr. Goldfrank and Marcy Pressman, the HHC leadership including Alan Aviles (President), Ramanathan Raju, MD, (Executive Vice President, Medical and Clinical Affairs), LaRay Brown (Senior Vice President of Corporate Planning, Community Health and Intergovernmental Relations), Salvatore Russo (Executive Senior Counsel for Medical/Legal Affairs), Lynda Curtis (Sr. VP and Executive Director of Bellevue), and Eric Manheimer, MD (Medical Director of Bellevue) have approved the internal stakeholder meetings to be held at Bellevue Hospital, FDNY, and the NYODN. Recently, we received approval from the HHC leadership to begin our community outreach efforts and market research. These efforts will be led by the NYODN personnel.

The fourth challenge was the organization of the community outreach campaign in a fiscally responsible and timely manner to achieve community support prior to beginning the UDCD program. Efforts have been made to scale down and merge community outreach efforts to achieve this goal. Current ongoing negotiations will be resolved shortly so that the public relations campaign may be initiated immediately after the UDCD protocol is derived through the consensus approach as outlined in this interim report. The community outreach campaign will be conducted through novel approaches that maximize efficiency in addition to standard community board meetings and community stakeholder focus groups. Final plans are being discussed as we have only recently received approval to initiate these efforts.

The fifth challenge is to obtain approval from New York State (NYS) EMS to allow the dedicated EMT staff on the RORA ambulance to administer heparin to the potential donor immediately after the hands off period as proposed in the protocol. Traditionally, only paramedics in NYS are allowed to administer medication, and heparin is not currently among those medications approved even for paramedic administration. The Chief of FDNY EMS Field Services, John S. McFarland, has joined our research committee, and he along with Brad Kaufman, MD will present the research to the NY State and NYC divisional meetings to obtain a waiver of practice on deceased individuals for these personnel. Consequently, FDNY has drafted a proposal that will staff the RORA ambulance with dedicated EMTs so that there is no conflict of interest between these personnel and other FDNY EMS providers. The RORA program has been introduced to the NY State and Regional EMS meetings as well as a National EMS convention. Overwhelming support for the program was voiced at all three meetings and appropriate channels are being followed to obtain written authorization for the facilitation of the research program. Thus far, we have received approval to administer Heparin as part of the prehospital protocol, and we are negotiating as to the level of the personnel who may be trained in airway management (EMT, EMTi, or paramedic). Airway management of the intubated deceased patient will be a new responsibility for a New York EMT or EMTi. We

leadership, and Brad Kaufman, MD and John McFarland will present the program to the FDNY EMS union as well as state and division boards. Dr. Goldfrank is scheduled to present our progress to date at the HRSA Consensus Conference on Donation to be held April 1-2, 2008. The slides for this talk are available on our wiki for review (the file is over 8MB and may not be sent through traditional email).

7.) Data:

a. Number of patients/subjects enrolled

The formal program evaluation has not begun, but we have finished the internal stakeholder meetings. These meetings included representatives from Bellevue hospital (nursing, emergency physicians, trauma surgeons, transplant surgeons), FDNY EMS, and the NYODN. The data from these three meetings led to the derivation of our preliminary protocol. We have begun analyzing the qualitative data to triangulate the findings from the notes taken during the discussions.

Other data from this project included a GPS mapping of the Bellevue RORA catchment area supplied by Chief McFarland's staff and efforts are underway to estimate the number of potential donors the RORA might encounter given the staffing plan and the NYC EMS data on out of hospital cardiac arrests. Using data from Chief McFarland's office, accurate estimates of potential donors meeting the clinical criteria are being pursued by Fred Selck of the NYODN. We have preliminary estimates from our analysis and will confirm these estimates as more data are collected in the coming months.

b. Projected enrollment for next quarter

In the next quarter, we will finish the external stakeholder meetings as described. We will analyze this data to modify the protocol to address the concerns raised during the meetings. The data will also define the content for the ethical white paper to be drafted by Nancy Dubler. The public relations campaign will also be initiated, and data from that effort will contribute to protocol modification and acceptance. The RORA ambulance will be contracted, and preparations made to hire the labor and secure the equipment necessary for its initiation in January 1, 2008. Given the delay we encountered with our legal counsels, we are delaying the initiation of the program, so as to ensure that the communities accept the program prior to its initiation. Concurrent with this timeline, the organ donor family service counselors and FDNY EMTs will be hired 3 months prior to undergo training for this unique ambulance service.

8.) Date of Most recent IRB Approval/Denial/Exemption and expiration date

IRB approval was obtained November 26, 2007 with an expiration date of November 25, 2008. Enclosed is a pdf copy of the IRB approval letter.

**Institutional Review Board
NYU School of Medicine**

Veteran's Administration Hospital
Physical Address: 423 East 23rd Street | 10th Floor, West Wing | NY, NY 10010
Mailing Address: 550 1st Avenue | #VET 10th Floor, West Wing | NY, NY 10016



Initial Application: Expedited | Approved

29-Nov-2007

Expanding Opportunities for UDCD

Principal Investigator	Dr. Goldfrank, Lewis R	Review Type	Administrative Action <input type="checkbox"/> Initial Application
Phone	+1 212 263 5022	Submitted	21-Nov-2007
IRB#	07-902	Email	lewis.goldfrank@nyumc.org
Location(s) Used	Bellevue Hospital Center	Perf. Period	25-Nov-2007 - 25-Nov-2008
Review Date	26-Nov-2007	Board/Meeting	Board A on 04-Dec-2007
Sponsor	AHRQ/Agency for Healthcare Research and Quality-	Subjects	(total) (approved)

The current IRB status of your study is: Approved

The study has been granted Expedited review in accordance with 45 CFR 46.110:

RE: H#07-902
Elan Czeisler
Director, Institutional Review Board (IRB)
OHRP #FWA00004952

29-Nov-2007

Notes:

1. You must submit all changes to this study (e.g., *protocol, recruitment materials, consent forms*, etc.) in writing to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. You must report all adverse and/or unanticipated event(s) that occur during the course of this study to IRB in writing in accordance with IRB Policy.
3. Use only IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Do not use expired consent forms.
4. You must inform all research staff listed on this study of changes or adverse events which occur.
5. IRB's approval is valid until the end date of the performance period indicated above. A reminder for renewal should be e-mailed to you from the IRB 90, 60 and 30 days before this study's approval is scheduled to expire. However, you are responsible for submitting all renewal materials at least eight weeks before expiration regardless of whether or not you receive a reminder notice.
6. All IRB policy documents can be found on our website: <http://www.med.nyu.edu/irb/>
7. Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
 - NYU Hospital Center (Tisch Hospital/Rusk Institute/Co-op Care) Irene Kreusher, VP, Tisch Hospital Administration. 212-263-2020
 - Bellevue Hospital Mr. Anand Veereraj, Research Administrator, Bellevue Hospital Research Committee. 212-562-4176; Ms. Setira Simmons, Research Administrator, Bellevue Hospital Research Committee. 212-562-7075
 - GCRC (General Clinical Research Center) Hal Rosenblatt, Research Grants Coordinator. 212-263-7900; 212-263-8040
 - VA Medical Center Administrator, R&D. Sub-committee for Human Studies. 212-686-7500 x7474

o HJD (Hospital for Joint Diseases) Dr. Paul Gusmorino, Liaison Coordinator. Institutional Board of Research Associates. 212-598-6368

The IRB may terminate studies that are not in compliance with NYU Medical Center/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the Federal Government. Direct IRB questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, etc.) to phone 212-263-4110, fax 212-263-4147 or email IRB-info@med.nyu.edu.

New York University School of Medicine's Institutional Review Board

550 First Avenue | #VET 10th Floor, West Wing | New York, NY 10016

phone 212-263-4110 | fax 212-263-4147 | email IRB-info@med.nyu.edu | web <http://www.med.nyu.edu/irb>

The NYU SoM IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations