BUREAU OF HEALTH PROFESSIONS

CLINICAL INTERVENTIONS FOR INCREASING ORGAN PROCUREMENT PROGRAM

JUNE 12, 2007

OBJECTIVE REVIEW COMMITTEE FINAL SUMMARY STATEMENT

APPLICATION NUMBER:	44014
APPLICANT NAME:	University of Pittsburgh
LOCATION (City, State):	Pittsburgh, PA
ORC SCORE:	87

CRITERION 1. Need

Strengths:

- The application recognizes the need for standardization and a systematic approach to a complex and time-sensitive event.
- The description of the need and availability is detailed and presents a step-wise approach.
- Involving a rapid response team provides non-biased personnel to address patient management and family support.
- The applicant proposes to expand their successful donation after cardiac death (DCD) program, to include uncontrolled donors after cardiac death (UDCDs).

Weaknesses:

- None noted.

CRITERION 2. Response

Strengths:

- The project promotes educational ideas and processes to improve awareness and acceptance of UDCD.
- The web-based approach is widely available and may be applicable to a large cohort of people.
- The application is well focused in describing the project; the goals of the project are to establish a UDCD protocol that is transferable.
- The Condition T team will be comprised of multidisciplinary personnel that includes multiple stakeholders: OPO representatives, OR staff, ED staff, transplant surgeons, and hospital administration.

Weaknesses:

- It is unclear why the project will be transferred to the University of Michigan before demonstrating the effectiveness of the approach at the University of Pittsburgh.
- The application includes minimal description of how exactly response teams will be created.
- While the Condition T team involves transplant surgeon, the application does not indicate how their involvement in patient management will be appropriately limited.
- The applicant proposes using the Kootstra double balloon, triple lumen catheter to flush organs. Little mention is made of the difficulty in placing these catheters and the relatively high failure rate. The statement on page 12, "Because of the obvious similarities between the double-balloon triple lumen catheter insertion and other central venous line insertions…" is inaccurate. Additionally, utilizing this approach may preclude hepatic recovery.
- The application does not mention what perfusate will be used for rapid cooling. The application mentions that the use of this catheter can accommodate hepatic recovery.
- The number of UDCD organs expected to be procured is limited and unambitious.

CRITERION 3. Evaluative Measures

Strengths:

- Surveys and web-based education can be readily monitored and evaluated—this will allow for evaluation of the effectiveness of the project.
- The methods for in situ organ preservation are well established. This methodology may be effective in organ cooling and preservation.

Weaknesses:

- The application does not elaborate the metrics involved in the evaluation of the attitude assessment surveys.
- There is no control group to evaluate if the education improved the number of cases.

CRITERION 4. Impact

Strengths:

- The web-based approach and survey instruments are readily transferable.
- Practicality is demonstrated for institutions of similar capabilities.
- The methods are simple, routinely practiced, and easily reproducible. The major strength of this project is transferability; the applicant has the experience to establish teaching methods for other medical centers.

- The consent process and in situ cooling are practical because of the involvement of rapid response team and the local organ procurement organization (OPO).
- The applicant intends to build upon their already nationally recognized skill sets regarding Crisis Team Training to create a comprehensive process and training package for UDCD.

Weaknesses:

- Replicability may be limited in the secondary center because of unique administrative and infrastructure support (e.g., lack of documented emergency physician commitment).

CRITERION 5. Resources/Capabilities

Strengths:

- The applicant has a long demonstrated experience with DCD and transplantation.
- There is knowledge and experience at the University of Pittsburgh in the development and implementation of rapid response teams.
- Investigators at the University of Pittsburgh (and the institution as a whole) are well trained and are able to complete the project.
- The resources of the WISER Center are well established for simulating complex medical situations.

Weaknesses:

- The project assumes a high level of competence (in cut-downs) among emergency department physicians, which may not be accurate or correctable through simulation.
- Other than a letter of intent from the Department of Transplantation, there is no documented support from the University of Michigan (particularly the emergency department) for the project.

CRITERION 6. Support Requested

Strengths:

- The identified personnel appear reasonable given the project scope.

Weaknesses:

- It is unclear why the project will be transferred to the University of Michigan before demonstrating the effectiveness of the approach at the University of Pittsburgh. Therefore, it is unclear whether the funds requested for the University of Michigan are reasonable.

- Supply expenses for the University of Michigan are inconsistent with supply costs at the University of Pittsburgh (for example, $5,000 to acquire a simulation trainer, but no request for disposables for the trainer).

BUDGET RECOMMENDATION

Budget Recommended:	As Requested: ☒	As Reduced (see below): ☐

Recommended Budget – to be completed during ORC *(if applicable)*:

Year	Recommended Federal Funding
01	$286,974
02	$326,103
03	$321,089
TOTAL	$934,166

Rationale for Budget Reduction *(if applicable)*:

RECOMMENDATIONS TO HRSA and/or APPLICANT

- Without buy-in of the emergency department at the University of Michigan, and without first showing the effectiveness of the methodology at the University of Pittsburgh, the budget may not reflect the cost of implementing the project at the University of Michigan.
- It is unclear whether or not expenses related to modifying simulation technology are reasonable.

Healthcare Systems Bureau
Clinical Interventions for Increasing Organ Procurement Grant Program (CIOP)
Application Number 44014

University of Pittsburgh
Conditions of Award

1. Please clarify why the project will be transferred to the University of Michigan before being implemented at the University of Pittsburgh. In this clarification please provide greater detail between the differences in supply costs between the University of Michigan and the University of Pittsburgh.
2. Specify the role of the transplant surgeon in the proposal and how conflicts of interest, either real or perceived will be avoided.
3. Please explain in greater detail how/when clinical staff will be trained to use the Kootstra double balloon, triple lumen catheter. Please also address comments made by the Objective Review Committee that use of this catheter may preclude hepatic recovery.
4. 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.
5. Please provide documentation of emergency physician and emergency department commitment to this project from the University of Michigan.

PANEL

AUG 17 2007

CIOP
3880702
Venus
WALKER

DRAFT

Kozlovsky, Bernard (HRSA)

From: Bongiorni, Karen [bongiornikl@ccm.upmc.edu]
Sent: Wednesday, August 15, 2007 7:14 PM
To: Kozlovsky, Bernard (HRSA); Barney, Brad (HRSA)
Cc: DeVita, Michael; tpaulson@pitt.edu
Subject: Response to Questions Regarding Application #44014-Dr. Michael A DeVita
Attachments: ED Support Letter.pdf; Response to questions.doc

Dear Dr. Kozlovsky and Mr. Barney: Attached please find an advance copy of Dr. DeVita's response to your questions on the above-referenced proposal, along with a copy of a letter of commitment from the University of Michigan for support of an ED advocate. An official copy of the that includes institutional endorsement will follow separately. After you have had an opportunity to review the information, please do not hesitate to contact us if you have questions.

Sincerely,

Karen L. Bongiorni
Sr. Grants Administrator
University of Pittsburgh
Department of Critical Care Medicine
642B Scaife Hall
3550 Terrace Street
Pittsburgh, PA 15261
Phone - 412-647-5990
Fax - 412-802-3308
bongiornikl@ccm.upmc.edu

<<ED Support Letter.pdf>> <<Response to questions.doc>>

DRAFT

Office of Clinical Affairs
C201 Med Inn Building, SPC 0825
1500 E. Medical Center Drive
Ann Arbor, Michigan 48109-0825

Darrell A. Campbell, Jr., M.D.
Chief of Staff

Telephone: (734) 936-5814
Fax: (734) 936-9406

August 15, 2007

Dear Dr. DeVita,

I am writing to you in my role as Chief of Clinical Affairs at the University of Michigan Hospitals and Health Centers. You have requested a letter of support for the project entitled "Development and dissemination of a rapid response system for uncontrolled donation after cardiac death". This collaborative project includes the University of Pittsburgh, the Center for Organ Recovery and Education, Gift of Life Michigan, and of course our medical center. In particular I am requested to provide documentation of the Emergency Department's commitment to the project, which includes of course, a physician leader in that site.

We agree that even though the care of the donors in the Emergency Department at the University of Michigan will be the responsibility of the transplant team, an emergency department leader and advocate will be an important promoter of success. We have identified Dr. William Barsan for this role. Dr. Barsan will be responsible for being a liaison for the emergency department nursing and physician staff. He will coordinate the educational process to make sure that all key personnel undergo the web-based training module being created as part of this project. He will also be responsible for fostering clinical implementation of the project. We expect the workload to be minor in terms of time commitment, but essential in terms of its importance to the success of the project. We request that a 0.05 FTE be allocated to support this person's effort for three years.

Thank you for including us in this important proposed project. Please let me know if I can answer any additional questions for you.

Sincerely,

DRAFT

Darrell A. Campbell, Jr., M.D.
Henry King Ransom Professor of Surgery
Chief of Clinical Affairs

August 15, 2007

Bernard F. Kozlovsky, MD, MS
Medical Officer
HRSA-Division of Transplantation

Re: HRSA Application #44014, Dr. Michael A. DeVita; Uncontrolled DCD

Dear Dr. Kozlovsky:

I am writing in response to your request for additional and clarifying information about our grant proposal. Below are responses to your questions as stated:

1) Please clarify why the project's interventions will be transferred to the University of Michigan before being implemented at the University of Pittsburgh.

I have reviewed the document and was not able to find where we stated that the University of Michigan would precede the University of Pittsburgh, however, I understand that we were not sufficiently clear in our presentation. The plan is to implement each stage at the University of Pittsburgh, and after 1-2 quarters of experience, then implement the same stage at the University of Michigan. The timeline/work plan on page 19 of the narrative has this information. For example, we will implement catheter skills training at Pitt in 6/08, and then on 9/08 at Michigan. Both time frames are two quarters, so there is a little overlap. The same sequence exists for Data collection, procurement, and analyzing data. I apologize for any ambiguity.

2) Please provide documentation of emergency room physician and departmental commitment to the project by the University of Michigan.

The University of Michigan, unlike the University of Pittsburgh, has 24 hour on-site attending-level staffing of the hospital by a transplant surgeon. That being the case, the University of Michigan will not need the same level of support from the emergency physicians, or the emergency department. The ED duties will be to identify potential UDCDs, and put out the Condition "T" call. They will not have any post mortem care duties. Therefore the ED educational requirement will be to train staff regarding what UDCD is, why it is important, and what is required of them. This information is included in the on line course we are designing here at U Pitt, so there is no additional cost to University of Michigan for training development. There is a time requirement for nursing and physician competencies, but this is an unfunded project and is being made part of the annual staff training.

3) Once commitment is obtained, please verify that the costs associated with implementation of the interventions at the University of Michigan are accurate and reflect their costs.

Upon review of our budget, and our consideration of your comments, we agree that an ED Champion will be important to successful implementation of both the educational process as well as the DCD implementation. Towards that end, we have added a .05 FTE for an ED physician leader for all years of the grant. This person will be responsible for leadership in making sure that ED staff complies with training, is available to answer questions, and to provide clinical leadership in support of the program. Dr. William Barsan will be the emergency department leader and advocate for this program at the University of Michigan; a letter confirming his participation is attached. The impact that Dr. Barsan's effort will have on our project's direct cost budget totals $11,550 in year 1, $11,897 in year 2, and $12,254 in year 3. Please identify what documentation you will need from us in order to consider this addition to our budget proposal.

I hope that this clarifies our grant proposal for you sufficiently, and do not hesitate to contact us if you require additional information or have questions on that which has been provided here. Thank you again for considering our proposal.

Sincerely,

Michael A. DeVita, MD
Professor of Critical Care Medicine
Principal Investigator

CC: Brad K. Barney
Grants Management Specialist

DRAFT

Kozlovsky, Bernard (HRSA)

From: Kozlovsky, Bernard (HRSA)
Sent: Friday, April 04, 2008 2:10 PM
To: Lewis.Goldfrank@nyumc.org; 'goldf103@med.nyu.edu'
Cc: 'Steve Wall'; McLaughlin, Chris (HRSA); Barney, Brad (HRSA); Humphrey, Judy (HRSA)
Subject: Grant-R38OT08761 Period 2- 09/01/08-08/31/09 Non Compete Application
Importance: High
Attachments: 2008noncompeteguidancefinaldocumentHRSA 5-R38-08-001 CIIOP FINAL.doc

Dear Dr Goldfrank:

As you are aware, HRSA requires a Non-Compete application for the 2nd and 3rd years of your grant. Attached is the Non-Compete Guidance for year 2. The application period just opened on March 31, 2008 and the application is due in Grants.gov by May 1, 2008 with supplemental information due by May 15, 2008 as per the Guidance.

To access non-compete Guidance and application online go to: http://www.grants.gov/applicants/apply_for_grants.jsp and click on "APPLY FOR GRANTS" then "Download a Grant Package." Enter "funding opportunity #: 5-r38-08-001 followed by download of guidance and application.

Before you can complete an application you **MUST** have the PureEdge Viewer or compatible Adobe Reader installed.

Please feel free to contact me should you have any questions.

Bernard F Kozlovsky, MD MS
Medical Officer
HRSA-Division of Transplantation
301-443-0565
bernard.kozlovsky@hrsa.hhs.gov

Associated Press

Related News

New York to Test 'Rapid-Organ-Recovery Ambulance'
Wall Street Journal Blogs - 3 hours ago

Full coverage »

NY considers creating 'organ-removal' ambulance

By DAVID B. CARUSO – **20 hours ago**

NEW YORK (AP) — Saving the living has always been the No. 1 priority for a New York City ambulance crew. But a select group of paramedics may soon have a different task altogether: saving the dead. The city is considering creating a special ambulance whose crew would rush to collect the newly deceased and preserve the body so that the organs might be taken for transplant.

The "rapid-organ-recovery ambulance," still in the early planning stages, could raise a host of ethical questions and strike some families as ghoulish. But top medical officials in the Fire Department and Bellevue Hospital say it has the potential to save hundreds of lives.

Generally in the U.S., only people who die at hospitals are used as organ donors, because doctors are on hand with life-support machinery and other equipment to preserve the organs and remove them before they spoil. Surgeons have only a few critical hours before kidneys, livers and other body parts suffer damage that renders them unusable.

Dr. Lewis Goldfrank, the director of emergency medicine at Bellevue, said the ambulance project could spark an "amazing transformation" by substantially increasing the pool of donors. The system would be one of the first of its kind in the U.S., although similar ambulances have operated successfully in parts of Europe, he said.

The transplant ambulance would turn up at the scene of a death mere minutes after regular paramedics ceased efforts to resuscitate a patient. The team would begin work almost immediately, administering drugs and performing chest compressions intended to keep the organs viable.

Sometimes, those steps would be taken before getting approval from a relative and without knowledge of the departed's wishes regarding organ donation.

Any organ removals would be done at the hospital only. And no organs would be removed without getting the family's express consent.

But experts in medical and legal ethics said they still see potential for trouble.

"Starting this process without knowing whether the decedent wanted to be a donor could be a problem," said Maxwell Mehlman, director of the Law-Medicine Center at Case Western Reserve University in Cleveland.

Distraught relatives could be unnerved by the site of a transplant team arriving so soon after a death. Some might have a religious objection to organ donation, and be enraged to learn that a body had been moved and injected with fluids.

Other families might also — rightly or wrongly — question whether the paramedics curtailed their lifesaving efforts because a patient had valuable organs.

"A lot of people don't trust the medical system to begin with, and in the city, you have additional class and race issues to deal with," said Arthur Caplan, a professor of bioethics at the University of Pennsylvania. "I could very easily see a family saying, 'If it was a white, rich person, that person would have been saved. But instead you've sent the meat wagon.'"

Doctors working on developing a pilot program say they realize the sensitivity of the issue and are building precautions into the system, which would start with just one ambulance.

The project's ethics consultant, Nancy Dubler, director of the division of bioethics at Montefiore Medical Center, said there would be an "absolute barrier" between the medical personnel involved in the lifesaving effort and those working on the organ recovery team.

Paramedics responding to an emergency would not be told whether there was a transplant crew waiting in the wings, and would have nothing to do with that process.

A separate supervisor would make the call on whether to dispatch the organ-recovery ambulance, and that team would be barred from arriving until five minutes after a formal declaration of death.

Only cardiac arrest patients who die of natural causes would be considered candidates for

the program.

The organ-recovery team would also travel with a counselor who would make every effort to get a family's consent before the body was moved or touched.

"That's a tricky conversation," acknowledged Dr. David Prezant, the Fire Department's chief medical officer. He said grieving relatives might expect to be asked about organ donation at a hospital, but are certain to be caught off guard if the topic is broached in the field.

The city has received a $1.5 million, three-year grant from the federal government, but there is no set date yet for when the ambulance might begin operating.

Researchers say their next step is to consult with lots of New Yorkers, including religious leaders and members of the Manhattan neighborhood around Bellevue where the ambulance would operate.

"If everyone isn't comfortable with the answers, we won't be moving forward to a pilot phase," Dubler said.

Goldfrank estimated that 22,000 people die at home each year in the U.S. who might be able to donate organs through such a program, although he added that it would probably only be workable in big, dense cities.

Opinion surveys in the U.S. routinely find that a majority of Americans are willing to donate their organs. In New York, more than 1.4 million people have signed an organ donor registry maintained by the state.

"Several hundred people die every month waiting for organs," said Dr. Richard O'Brien, an emergency physician at Moses Taylor Hospital in Scranton, Pa., and a spokesman for the American College of Emergency Physicians. "This could be a way to make organs more reliably available to people who desperately need them."

Hosted by Google

Copyright © 2008 The Associated Press. All rights reserved.