

**BUREAU OF HEALTH PROFESSIONS  
CLINICAL INTERVENTIONS FOR INCREASING ORGAN PROCUREMENT  
PROGRAM**

**JUNE 12, 2007**

**OBJECTIVE REVIEW COMMITTEE FINAL SUMMARY STATEMENT**

<b>APPLICATION NUMBER:</b>	<b>44020</b>
<b>APPLICANT NAME:</b>	<b>New York City Health &amp; Hospitals Corporation</b>
<b>LOCATION (City, State):</b>	<b>New York, NY</b>
<b>ORC SCORE:</b>	<b>84</b>

**CRITERION 1. Need**

**Strengths:**

- The applicant understands the problems of organ shortage for transplantation and in the introduction chapter this issue is well described and discussed. The application clearly describes the methodology and various problems that could have a negative effect on the consent process and organ donation. The application documents the application of technology and the need for ethical issue evaluation.

**Weaknesses:**

- The role of the transplant surgeon in the project is unclear, and may cause a potential conflict of interest.

**CRITERION 2. Response**

**Strengths:**

- The goals and objectives are well described. The goal is to tap new donor pool and expand the organ availability.
- The methodology includes the consent process; the follow-up of recipients after transplantation, and the collection of data for both donor and recipient outcomes.
- The bioethicist, as a member of the research team, will be an asset to this project. Ethical aspects of the project will be overseen in an effective manner.
- The applicant proposes to be the first program to implement the Madrid process in the U.S.
- The consortium is well structured to involve important stakeholders (e.g., EMS, ED, bioethicist, hospital association, etc.).
- The investigator will be using in situ cooling technique to preserve the organs for transplantation. They also intend to utilize EMT and FSC technicians to initiate and

sustain cardiac massage to keep the organs perfused after cardiac arrest in the field before the patient is brought to the ED. These techniques will contribute to the success of the project.

- The supplies to be used for rapid cannulation for in situ cooling will be stored for rapid availability.
- There is coordination between the ED, the consent obtaining process, and EMS technicians.

**Weaknesses:**

- The consent process may be difficult to conduct within the 2 hour period after cardiac arrest. In such cases there is no alternate plan proposed.
- The anticipated timeline to achieve buy-in from the public and public officials seems inadequate to meet the objectives.
- The in vivo perfusion to keep the organs cold and preserve them for transplantation depends on rapid cannulation of femoral vessels, which may be difficult in a cardiac arrest patient.
- There is a lack of clarity in the community notification process, which allows for procedures without direct informed consent (including how this will be evaluated and approved by the IRB and how the process will be implemented).
- The timeline is markedly unrealistic to meet the objectives.
- The proposed methodology (i.e., the Rapid Organ Response Ambulance will operate for one shift per day) may limit potential candidates to one-third.

**CRITERION 3. Evaluative Measures**

**Strengths:**

- The proposed evaluations of the project are appropriate and include the staff necessary to carry out the calculations.

**Weaknesses:**

- There is a lack of detail regarding metrics concerning the cooling process.

**CRITERION 4. Impact**

**Strengths:**

- The approach proposed is innovative for the U.S.
- General protocols and guidelines formulated as a result of this study would be beneficial for replicating the approach in other locations.

**Weaknesses:**

- Maintaining the rapid response team as proposed may be expensive, which may hamper replicability and transferability.
- It is unclear how the unique cultural and political aspects of New York City will hamper the replicability and transferability of the project.

**CRITERION 5. Resources/Capabilities**

**Strengths:**

- The project requests appropriate funds for personnel who will be on call and will be available on an emergency basis.
- Current personnel proposed have demonstrated experience within their given disciplines.

**Weaknesses:**

- Training and retaining personnel to perform rapid cannulation, obtaining consent, and locating the family may be difficult to achieve.
- It may be difficult and time consuming to get buy-in from all the necessary city and civic organizations to successfully administer this program.
- The application does not adequately discuss the time and effort necessary to achieve community notification.

**CRITERION 6. Support Requested**

**Strengths:**

- None noted.

**Weaknesses:**

- The allocation of time for the principal investigator (PI) and co-investigators is not justified as adequate for the success of the project.
- There is concern about the availability of the PI and co-investigators. The application does not demonstrate that the scope of their current duties will allow for the percentage allocation to the project.
- There is concern that the public relations expense and campaign could be substantially more than is anticipated.