

- “Evidence Based Evaluation and Acceptance of Donor Hearts for Transplantation”
- Prospective, observational study aiming to enroll a cohort of 5000 DNDD organ donors spanning 5 years
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Despite the availability of successful medical therapies for end-stage heart failure, and mechanical circulatory support, heart transplantation remains the best option for appropriate candidates with end-stage heart disease (Stehlik, 2012). An estimated >20,000 patients could benefit from this life-saving procedure each year, however only 1,949 heart transplants were performed in the United States in 2011, with a concurrent waiting list mortality of 11.6 per 100 wait-list years (SRTR annual data report, 2011). The severe and persistent shortage of donor organs considerably limits the availability of heart transplantation. Additionally, approximately 65% of available donor hearts are discarded because of stringent acceptance criteria that have not been critically evaluated (Khush, 2013). The goal of this study is to help achieve the safe liberalization of donor heart acceptance practices and thus result in an increase in heart transplants performed nationwide.

To this end, we are conducting a prospective study focused on the standardized collection of data crucial to cardiac donor evaluation. The study has three primary aims: (1) to identify clinical correlates of cardiac function in potential donors being evaluated for heart transplantation, (2) to prospectively study reasons for non-acceptance of hearts offered for transplantation, (3) and to develop clinical tools to assist transplant centers with real-time decisions regarding donor heart acceptance. Data will be collected on a cohort of 5000 donors managed by 7 OPOs across the United States over the course of 5 years. The data collected will be used to create evidence-based clinical tools, such as risk calculators, that can be used in transplant centers when evaluating organ offers.

All DNDD donors with research authorization, between the ages of 18-65, HIV and HCV negative, will be considered eligible for enrollment into the study.

#### References:

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