

## Research Portfolio Online Reporting Tools (RePORT)

Project Information ?

1R01HL151736-01

DESCRIPTION	DETAILS	RESULTS	HISTORY	SUBPROJECTS
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<b>Project Number:</b> 1R01HL151736-01	<b>Contact PI / Project Leader:</b> <a href="#">WEISS, WILLIAM J</a>
<b>Title:</b> FINAL PRE-CLINICAL STUDIES FOR A VENTRICULAR ASSIST DEVICE FOR INFANTS	<b>Awardee Organization:</b> PENNSYLVANIA STATE UNIV HERSHEY MED CTR

**Abstract Text:**

ABSTRACT The situation for infants and young children requiring mechanical circulatory support for bridge to transplant or recovery remains challenging. The under one year of age group has few options, although they are the largest age group for pediatric transplantation and have the highest waitlist mortality. Although adult VADs are sometimes used in larger children, the pump size and output mismatch are significant limitations. The Berlin Heart EXCOR VAD is the only device approved for patients under approximately 6 years of age, but thromboembolism and neurologic dysfunction occur at a rate 10 times higher than in adult VADs. The Jarvik 2015 Pediatric VAD is in early clinical testing but there are limitations to its use in infants and for right heart support. The objective of this proposal is to complete the pre-clinical testing of the Penn State Infant Ventricular Assist Device (VAD) which will be a safer VAD for left or right support. The Infant VAD has been tested as a Left Ventricular Assist Device (LVAD) in 35 animal studies, and has demonstrated excellent biocompatibility. Despite an aggressive protocol in which there has been little to no anticoagulation, there has been no clinically evident thromboembolism or end organ dysfunction. The Penn State Infant VAD is a pneumatic pulsatile device. Although pulsatile VADs have been replaced by continuous flow pumps in adults, there are advantages to the pulsatile approach in infants. These include a low risk of thromboembolism and pump thrombosis with low levels of anticoagulation, flexibility in cannulation for LVAD, RVAD or BiVAD support, automatic preload-sensitive control of pump output, physiologic pulsatility, the absence of net zero or negative blood flow through the VAD at low pump speed which occurs in rotary pumps, and absence of acquired von Willebrand syndrome. We propose to complete the studies required for an IDE submission to the FDA under the Early Feasibility Study program. The specific aims are: Aim 1. Complete design controls and manufacturing process development for the VAD and cannulae, including a new inlet cannula for the RVAD. Aim 2. Complete the design of the portable pneumatic Driver to support an Early Feasibility Study. Aim 3. Perform in vitro verification testing of the final pump and driver in the LVAD, RVAD, and BiVAD configurations to demonstrate hemodynamic performance and acceptable hemolysis. Aim 4. Demonstrate safety (acceptably low thromboembolism and normal operation) of the final pump and driver in the LVAD and RVAD configurations in the high flow (3) and low flow ranges (3). Aim 5. Complete the pre-IDE documentation, design the EFS clinical protocol, hold a pre-sub meeting with FDA, and prepare an IDE submission.

**Public Health Relevance Statement:**

Project Narrative The objective of this project is to complete the pre-clinical testing of a Ventricular Assist Device (VAD) for infants to support their circulation while waiting for a heart transplant or in some cases, recovery. Design and testing have focused on developing a safe device with a low risk of stroke or neurologic dysfunction. A portable driver is being developed, and the VAD will undergo final testing in both left and right ventricular support configurations.

**Project Terms:**

1 year old; 6 year old; Acquired von Willebrand disease; Adult; age group; Animal Testing; Animals; Anticoagulation; Aorta; Attention; Berlin; biomaterial compatibility; Blood Circulation; Blood flow; Caliber; Cannulas; Cannulations; Child; Childhood; Chronic; Clinical; clinical investigation; Clinical Protocols; commercialization; cost; design; Development; Device Designs; Devices; Documentation; Engineering; Extracorporeal Membrane Oxygenation; Feasibility Studies; flexibility; Functional disorder; Future; Grant; Guidelines; Heart; Heart Transplantation; hemodynamics; Hemolysis; In Vitro; Infant; Investments; Lead; Left; left ventricular assist device; Left ventricular structure; manufacturing process development; Mechanics; meetings; mortality; National Heart, Lung, and Blood Institute; Neurologic Dysfunctions; operation; Organ; Output; Patients; Performance; Physiological; Population; portability; Positioning Attribute; preclinical study; Preclinical Testing; programs; Protocols documentation; prototype; Pulmonary Circulation; Pump; Recovery; research clinical testing; Risk; Safety; Speed; stroke risk; System; Technology; Testing; Thromboembolism; thrombogenesis; Thrombosis; Time; Transplantation; Venous Pressure level; Ventricular; ventricular assist device; Waiting Lists

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