Project Title: Implantation of an Intracortical Visual Prosthesis  
Principal Investigator: Philip Troyk, MD  

Background:  
Objective: Accomplish all of the necessary steps to prepare for the clinical testing of an intracortical visual prosthesis (ICVP) in humans.  
Hypothesis: Implementing a cortical visual prosthesis using smaller electrodes, closer to cortical neurons will produce higher specificity of neuronal activation and use substantially less stimulation charge injection, thus preventing electrode and tissue deterioration.  
Specific Aims: 1) Design, evaluate, and fabricate implantable electrode array/stimulator modules; 2) test the long-term biocompatibility and survivability of ICVP modules; 3) design and test a real-time psychophysical assessment and testing system for evaluation of ICVP recipients; 4) constitute a team structure within a clinical setting to prepare for the surgical implantation; and 5) prepare and submit an FDA investigational device exemption (IDE) application for a human trial.  
Study Design: A cortical visual prosthesis is technically feasible and may provide sensory benefit to the recipient. While earlier attempts to implement a cortical visual prosthesis relied upon macro electrodes placed within the subdural space, on the surface of the brain, an intracortical system would use micro electrodes that penetrate the visual cortex, extending directly to neuronal layers that process incoming visual information. Surface cortical stimulation systems have suffered from diffuse neural stimulation due to the relatively large separation between the electrodes and the neurons, and from the need to use excessively large stimulation currents that can cause electrode corrosion, pain, and seizures. Previous attempts to evaluate surface cortical systems in humans have not lead to successful demonstrations of functional vision restoration. The IIT ICVP is designed to use micro-sized wire electrodes that penetrated the visual cortex with tip sizes similar to individual neurons. The expectation is that smaller electrodes, closer to cortical neurons, will produce higher specificity of neuronal activation and use substantially less stimulation charge injection thus preventing electrode and tissue deterioration.  
Relevance: This project has the potential to have very high impact on combat veterans (and civilians) suffering from visual disability, because it aims to restore partial visual function that would be effective even for patients with retinal and/or optic nerve disease. This project is highly relevant owing to the increased number of returning war fighters with catastrophic loss of vision. According to reports in the popular press more than 1,100 veterans of the conflicts in Iraq and Afghanistan have undergone surgery for significant damage to their visual system. Currently there are approximately 157,000 veterans with blindness and over 100 from the Iraq conflict alone. According to research published in Survey of Ophthalmology the current percentage of all service-related injuries affecting vision is growing and has reached over 13% - the highest percentage since World War I. Historically, brain injuries and amputations have dominated non-fatal injuries, but there is a growing recognition that catastrophic eye injuries are occurring at almost twice the rate as injuries resulting in amputations. In the general population, there are approximately 1 million Americans with blindness, associated with an annual cost to the U.S. economy of $4 billion.