



IPRO-306: Midterm Presentation


**Planning for Human Implantation of
an Intracortical Visual Prosthesis**

What is Blindness?

- 10 million Americans
- 1.3 million are legal
- Legally Blind: central visual acuity of 20/200 in good eye (BPC), visual field of < 20 degrees
- 5.5 million > 64 years of age

BACKGROUND: NEURAL PROSTHESIS

- Use electrical stimulation of the neural tissue to restore function in individuals with disabilities due to damage of the nervous system
- Neural prosthetic devices process input from outside the body & transmit visual information to the nervous system
- Communicates with specific groups of neurons in the visual cortex to restore visual function



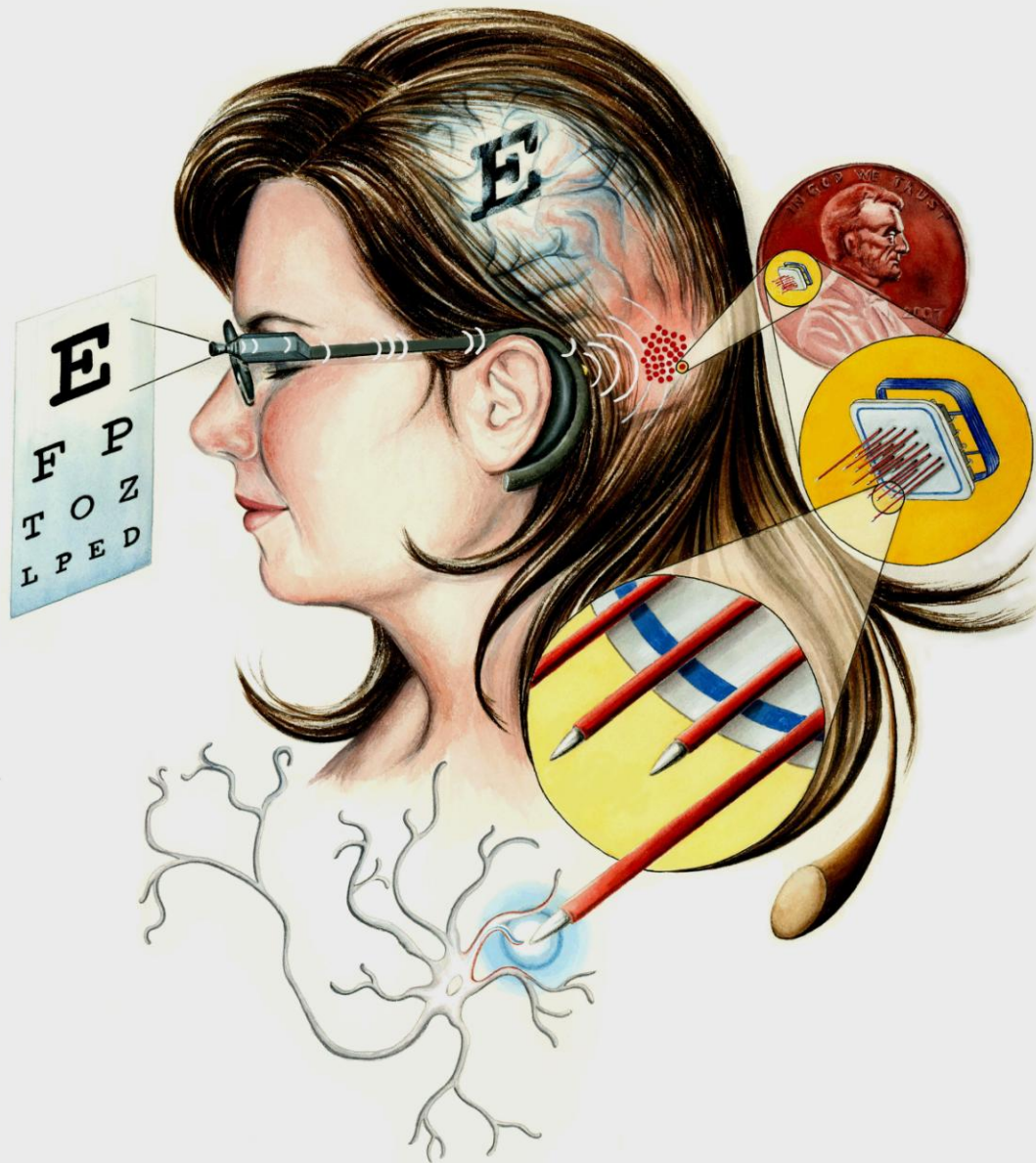
Goal: Research and compile the ethical, medical, psychological, engineering, regulatory, and media/political issues in determining the readiness of implementing an intracortical visual prosthesis in a human volunteer.

Sub Team Structure

- **Medical-** Andrew and Marin
- **Engineering/Regulatory-** Minh and Saurabh
- **Psychological-** Joshua and Peter
- **Ethical-** Joel and Kevin
- **Media/Politics-** Joel, Dawn, and Andrew

Advisors: Professor Troyk and Professor Huyck

Engineering an Intracortical Visual Prosthesis (IVP)



REGULATION BACKGROUND

Investigational Device Exemptions (IDE): General Considerations

- Our device is Significant Risk since it's implanted into the human body. (IDE regulation 21 CFR 812)
- Safety
- Effectiveness
- Volunteer safety is more important than success

IDE Performance Data

- Pre-clinical Data
- Animal Testing
- Clinical Data

DEVICE SAFETY

- **Electrode Safety Issues**
 - Electrode protection
 - Neuron Protection
- **Material Safety**
 - Fluids might leak though where electrodes and silicone meet
 - Difference in silicone grades

Future Plans:

- Study regulations for medical and industrial grade materials
- Identify procedures needed for human implantation (pre-clinical data, rehabilitation plan etc.)

Ethics Team

Current Goals

- Extensive research
 - Informed Consent
 - Education of Patient/Guardian
 - Risks vs. Benefits (if any)
 - Length of Care Term, Extent of Responsibility
 - Can volunteers benefit from new, improved technology

Future Plans

- Plan for handling issues with best possible results

Medical Aspects

Research the issues associated with implanting a visual prosthesis.

- Damage
- Reprogramming the brain
- Benefits?

Future Plans

- More fully understand the previously stated issues.
- Study if the device can keep up with degenerating conditions.
- Research the rehabilitation needed after implantation.

Psychology

Research

- Demographics
- “False Hope”
- Rehabilitation

Continuing Research

- Level of adjustment to disability
- Types of blindness

Feedback from the Community

- Surveys
- Focus groups

Media and Politics




Goal: Properly transmit the objective of product to the public

Current Research

- Regulations
- Educate public (show how product its advantages)
- Advertisement/Public Relations
- Public reaction and feedback
- Product information release
- Other applications of product

Future Research

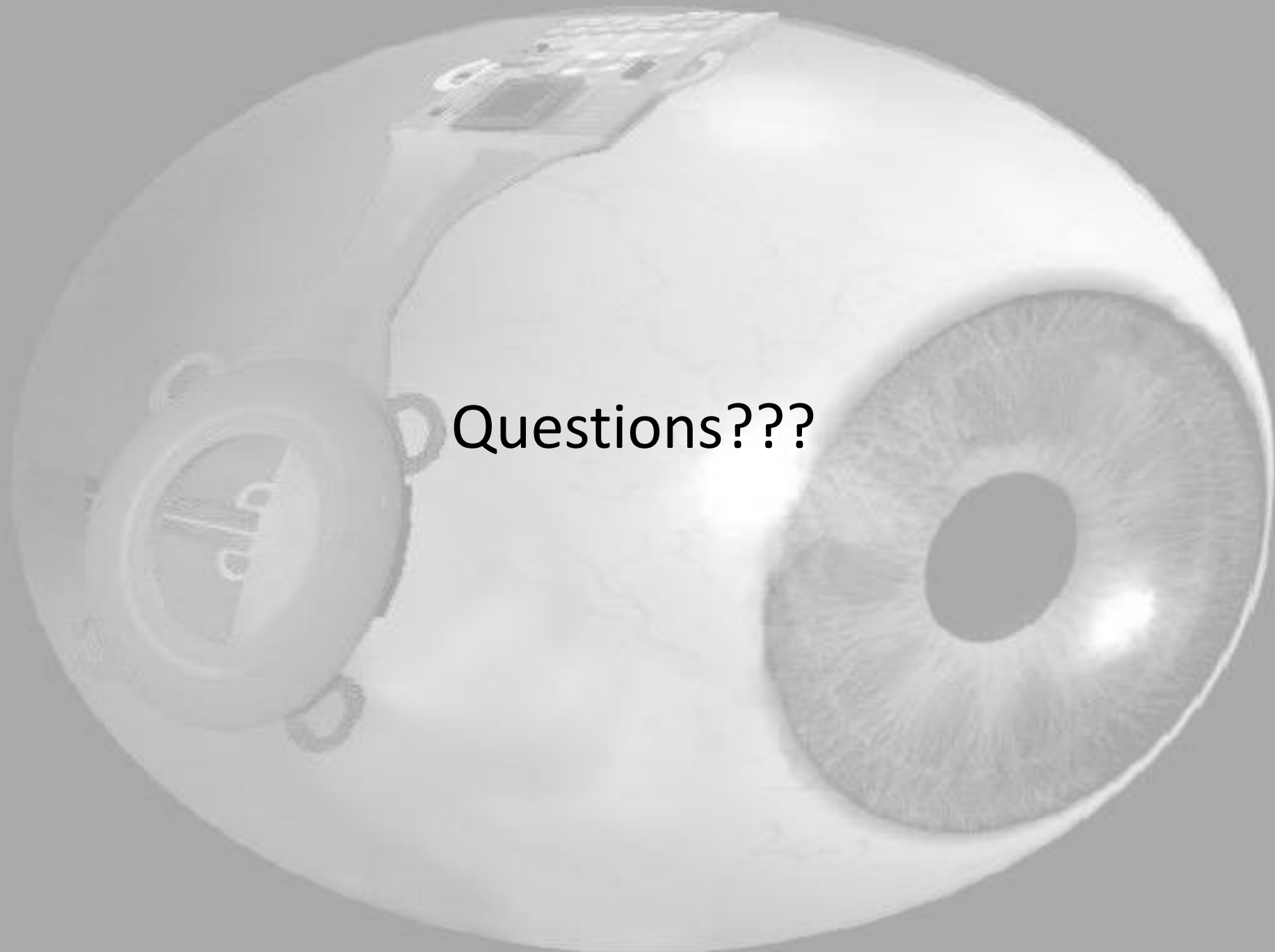
- Continue research
- Surveys (research how population would respond to the product)



Sponsors

– Intracortical Visual Prosthesis Team at IIT

- University of Chicago
- Huntington Medical Research Institute, Pasadena, CA
- EIC Laboratories , Norwood, MA
- Micro Probe Inc, Frederick Maryland



Questions???