PLANNING FOR HUMAN IMPLANTATION OF AN INTRACORTICAL VISUAL PROTHESIS
TEAM MEMBERS

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FACULTY ADVISORS

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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
Visual prosthetics have been implanted in patients around the world both acutely and chronically.

The Intracortical Visual Prosthesis Team (IVP) at IIT is developing a procedure and a device that can be implanted within the human visual cortex.

The IVP team is ready to proceed with implanting the device in a volunteer within the next few years.

The primary issues that will be focused on are the following aspects of IVP and human implantation:
- Engineer
- Medical
- Psychology
- Regulatory
- Ethics
- Politics/Media
GOAL

Research and understand the many issues that are associated with implantation of a device into human beings and to develop a guide that summarizes

Addresses these important topics to help facilitate the IVP team as it progresses into the implementation stage.
OBJECTIVES

Review available literature on visual prosthetics, focusing on intracortical, and make an assessment on the status of this technology.

Expand on the ethical, psychological, medical, regulatory, political, media, and engineering aspects of this new technology.

Make inferences regarding the overall effects of the multispectral aspects of Intracortical Visual Prosthetics on human volunteers, and create a plan bridging the gap between the current state of the technology and the point of the first human volunteer.
ENGINEER - RECOMMENDATIONS

- Accelerated Age testing of modules
- Long term system testing
- Need to determine safe stimulation
- Simulations of System
Simulation Setup Example

- Camera
- Processing Unit
- Primary Coil
- Secondary Coil
- Modules x63
- Stimulation Output x1008
- Converter
- Monitor
Qualifications for Volunteers

- Age 40-75
- Excellent Health
- Adventurous attitude
- Strong willed

More effective and less risky therapies than the prosthesis.

- Stem Cell
- Gene therapy
Prepare for:

- Extensive rehabilitation after implantation
- Careful monitoring of the subject’s mental state
- The potential for device abandonment

Length of project and provisioning of possible services to be established before implantation to prevent lapse of services/support

Potential for device failure needs to be addressed from a psychological perspective

Consideration of motivational factors for becoming subjects
The device is regulated under the US Food & Drug Administration (FDA).

The IVP device is intended to be implanted into human visual cortex so it must be certified as a Significant Risk Device (SR) as stated in the definition of a SR device under FDA.
Pre Investigational Device Exemption (IDE) meetings / teleconferences with IIT Institutional Review Board (IRB) and the Food and Drugs Administration (FDA).

Turn in IDE application form to the FDA and IIT IRB.

Need IRB and FDA approval before the Intracortical Visual Prothesis (IVP) research team and go ahead with the first clinical trials. It’s essential to have a system to record all pre/post clinical datas, consent forms & other related changes, documents.

Pre Markets Approvals (PMA) process.

Post approval process
ETHICS

- Proper information of potential volunteers
  - Content of informed consent form
  - Education Plan
- Assessment of risks and benefits
  - Evaluation of technical, medical, psychological risks and benefits
- Assessment of criteria compatible with the research
  - Volunteer selection criteria
  - Special considerations: vulnerable populations
Quantitative assessment of risks and benefits.

Children are not suitable for participation.

Other vulnerable groups would be considered under additional conditions.

Informed consent form to be signed only after successful completion of education process
MEDIA / POLITICS

- Information release methods/media
  - Literature Journals
  - Public Interviews
  - Press Conferences

- Public Education and Outreach
  - Information Sessions
  - Focus Groups
  - Feedback from Participating Volunteers
Transmit honest information to the public and volunteers through accurate negative and positive aspects of the device.

Develop a respected and validated public representation.

Publish news in respected journals.
Look into the final results from the focus groups that are currently in progress lead by Phil Troyk, Margaret Huyck and Frank Lane at Chicago Lighthouse for the Blind.

Re-evaluate the current recommendations as new information becomes available.

Develop a greater understanding of what affect visible parts of the device have on the decisions of possible volunteers.
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IIT- Intracortical Visual Prothesis research team & other reference sources.
QUESTIONS ? COMMENTS?

http://www.iit.edu/~ipro306f08