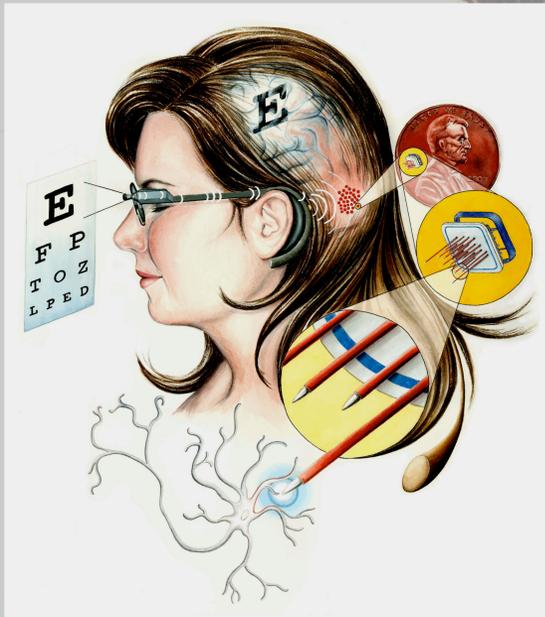


## RESULTS/ CONCLUSION

ENGINEER



Artist rendering of the Visual Prosthesis System- the picture shows a camera captures the image. Then the signal is form the came is sent wirelessly form the antenna to the modules in the visual cortex. When the modules get stimulated, the image that is captured from the camera, is perceived by the person.

### •Current status :

The electrodes, implant chip, camera and processing unit all have been bench tested independently but not as a whole system. It is very important to have the system working on the bench with any problems because after implantation no modifications can be made.

## REGULATORY

# PLANNING FOR HUMAN IMPLANTATION OF A CORTICAL VISUAL PROTHESIS

The device is regulated under the US Food & Drug Administration ( FDA).

- Our 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 regulation.

### •CHECKLIST :

- 1.Pre Investigational Device Exemption (IDE) meetings / tele conferences with IIT Institutional Review Board (IRB) and the Food and Drugs Administration (FDA).
- 2.Turn in IDE application form to the FDA and IIT IRB
3. Need IRB and FDA approval before the Intracortical Visual Prosthesis (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 and consent forms.
4. Pre Markets Approvals (PMA) process.
- 5.Post approval process.

## MEDICAL / PSYCHOLOGY

### Medical

- Surgical Aspect

Craniotomy, which is removal of the skull to perform surgery on the brain, is considered a major surgery, more so than any other. In many cases it is considered routine surgery, but it is nonetheless a very complex and risky procedure. Because of the complexity and risk of the operation, craniotomy is often used as a last resort where other options do not exist.

### •Risks :

- 1.Infection and bleeding
- 2.Occurrence of seizures
3. Affect of the device on the body or the affect the body will have on the device is not completely known .

### Psychology

We answered the following questions in our detail reports:

- 1.What do we know about the condition of blindness and visual impairments from a psychological perspective? How do these conditions impact the individuals who have them and will this device be capable of making an influence on any of these factors?
- 2.What barriers exist that may prevent potential subjects from wanting to be involved in the experimental phase of this device?

## ETHICS/POLITICS/MEDIA

The education plan on : Engineeringm, Risk/ Benefits, Rehabilitation, Extended care and Terms of Care. Consent forms will also be given out.

We also tackled and answered the following questions on our report:

1. How to best transmit /release correct information about the device to the public?
2. How to understand feedback about the device from current focus groups?

## OBSTACLES / FUTURE WORKS

- More tests needed to be done for the device in order to move on from the engineering phase.
- FDA regulation required an effective system to record every single details on the device, any changes that might be made in the future, pre/post clinical trial datas, any related materials.
- Therefore the team needed to consider how the information should be presented accurately to the people that are not involved in the Visual Prosthesis research.
- Researches should be narrowed down so it would encompass the Intracortical Visual Prosthesis Project.