PLANNING FOR HUMAN IMPLANTATION OF AN INTRACORTICAL VISUAL PROTHESIS

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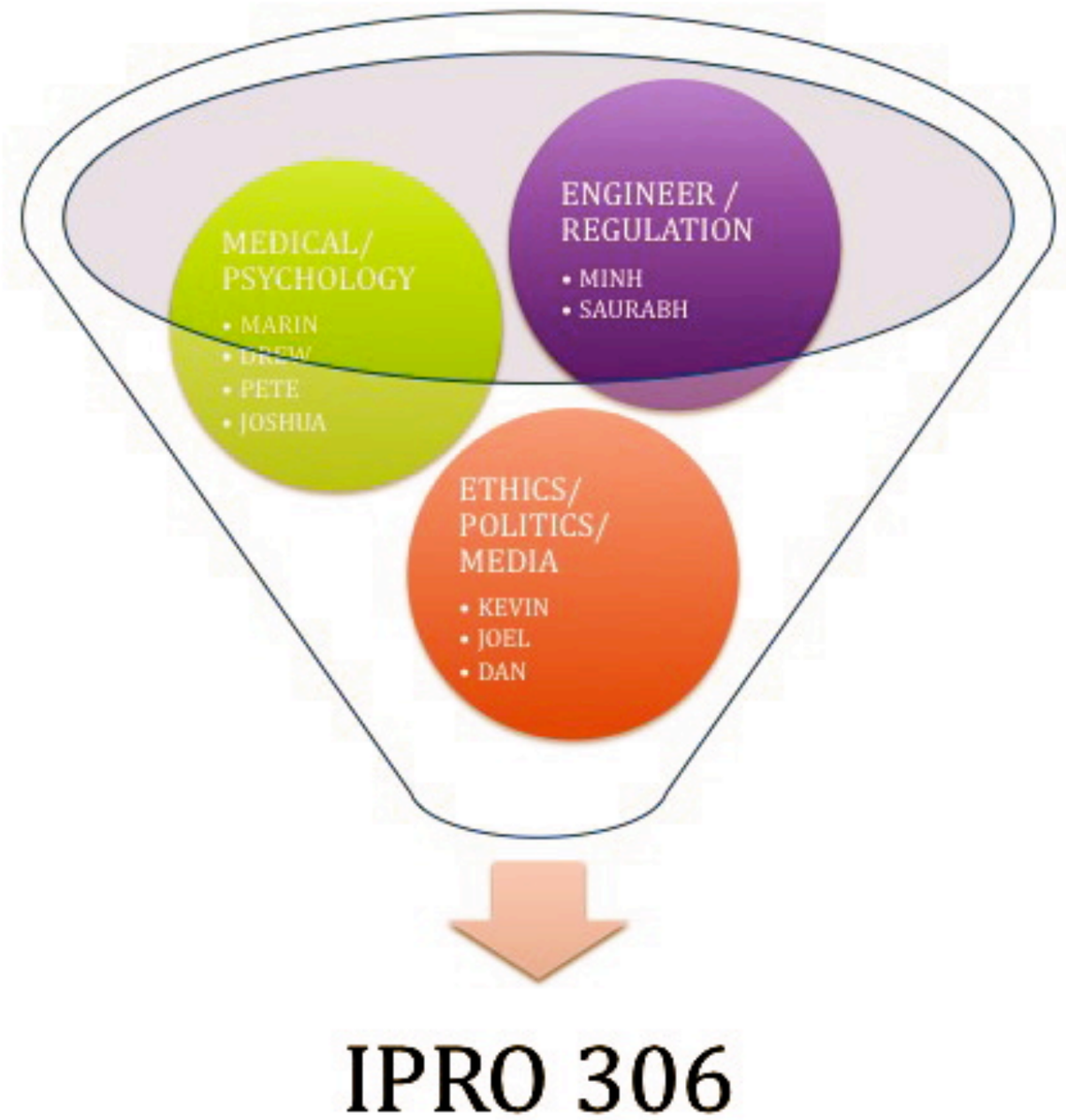
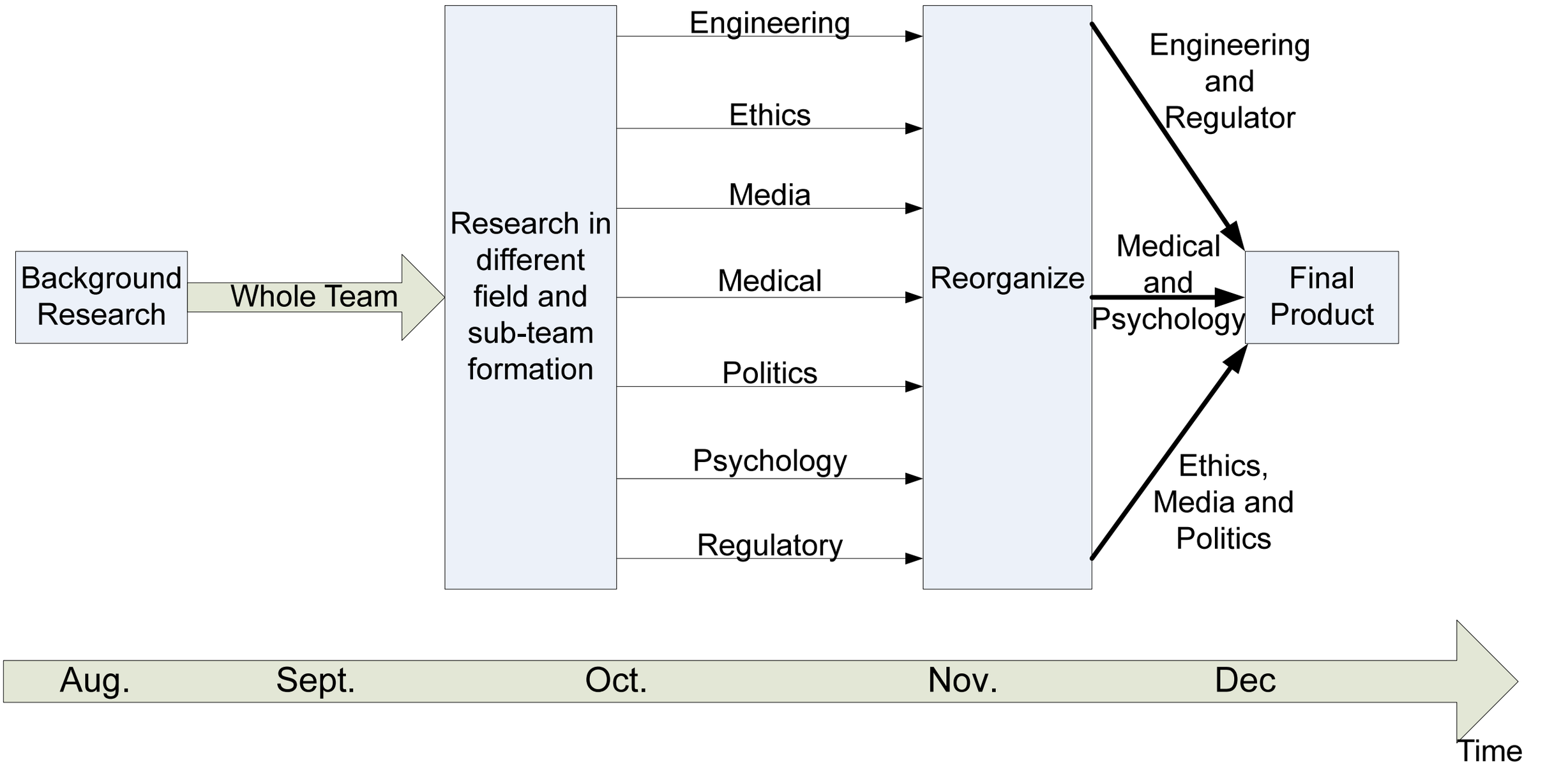


METHODOLOGY



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

- 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.

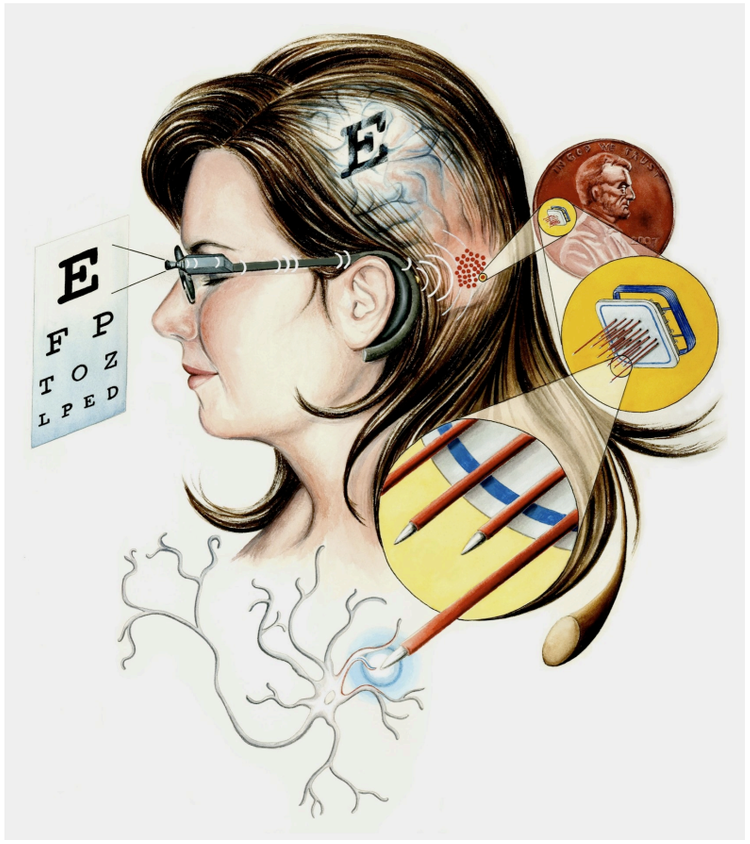
OBJECTIVES

- 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.

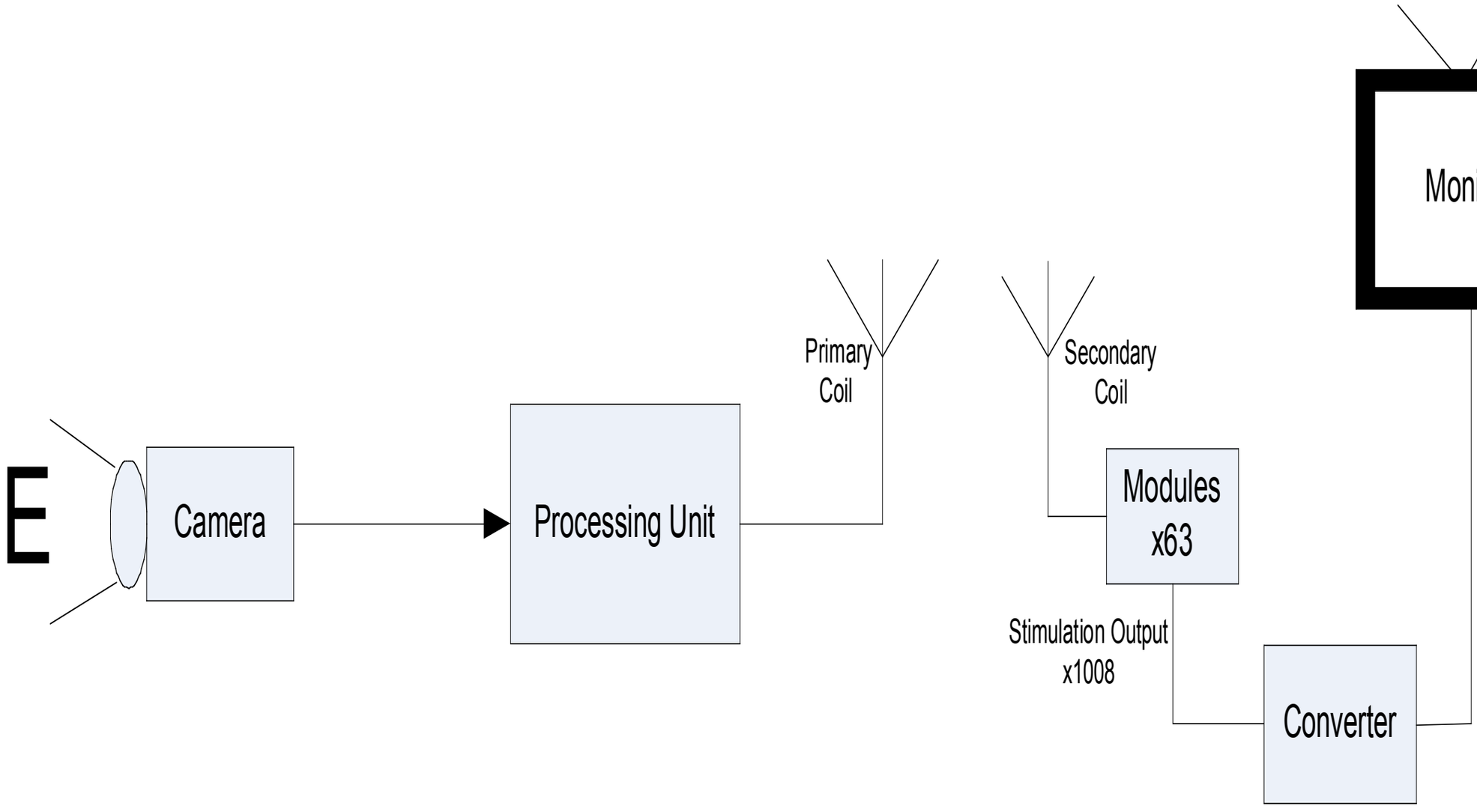
- Make inferences regarding the overall effects of the multispectral aspects of Intracortical Visual Prosthetics on human volunteers, and create a plan bridging the gap between the current state of the technology and the point of the first human volunteer.

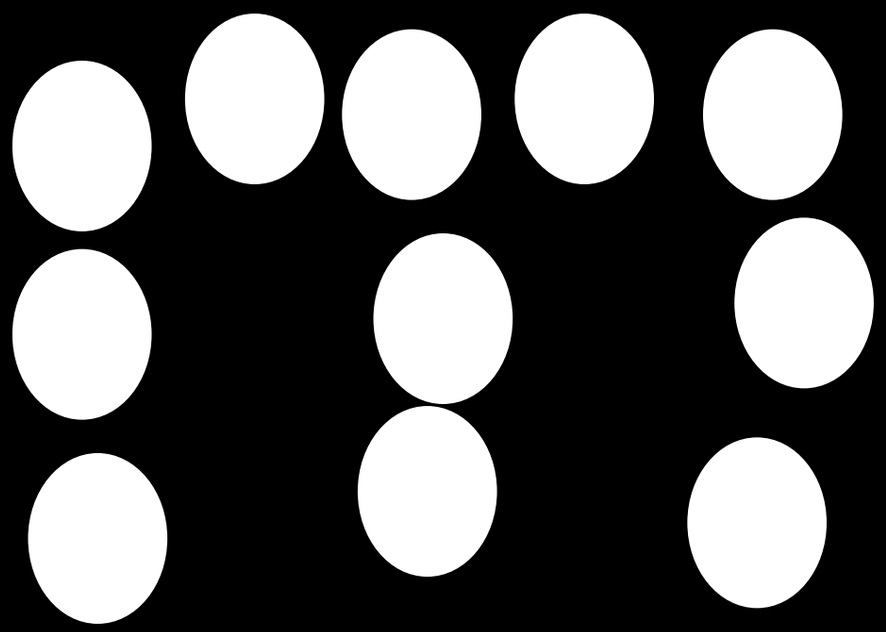
ENGINEER- RECOMMENDATIONS



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

Simulation Setup Example





MEDICAL

- 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

PSYCHOLOGY

- 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

REGULATORY

- 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

Subpart B--Application and Administrative Action

§ 812.20 - Application.
§ 812.25 - Investigational plan.
§ 812.27 - Report of prior investigations.
§ 812.30 - FDA action on applications.
§ 812.35 - Supplemental applications.
§ 812.36 - Treatment use of an investigational device.
§ 812.38 - Confidentiality of data and information.

Subpart C--Responsibilities of Sponsors

§ 812.40 - General responsibilities of sponsors.
§ 812.42 - FDA and IRB approval.
§ 812.43 - Selecting investigators and monitors.
§ 812.45 - Informing investigators.
§ 812.46 - Monitoring investigations.
§ 812.47 - Emergency research under 50.24 of this chapter.

Subpart D--IRB Review and Approval

§ 812.60 - IRB composition, duties, and functions.
§ 812.62 - IRB approval.
§ 812.64 - IRB's continuing review.
§ 812.65 - [Reserved]
§ 812.66 - Significant risk device determinations.

Subpart E--Responsibilities of Investigators

§ 812.100 - General responsibilities of investigators.
§ 812.110 - Specific responsibilities of investigators.
§ 812.119 - Disqualification of a clinical investigator.

REGULATORY- CHECKLIST

☑ Pre Investigational Device Exemption (IDE) meetings / tele-conferences 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

ETHICS- RECOMMENDATIONS

- 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

MEDIA / POLITICS - RECOMMENDATIONS

- 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.

FUTURE PLAN

- 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.

ACKNOWLEDGEMENTS

- Chicago Lighthouse
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- IIT- Intracortical Visual Prothesis research team & other reference sources.

QUESTIONS ? COMMENTS?