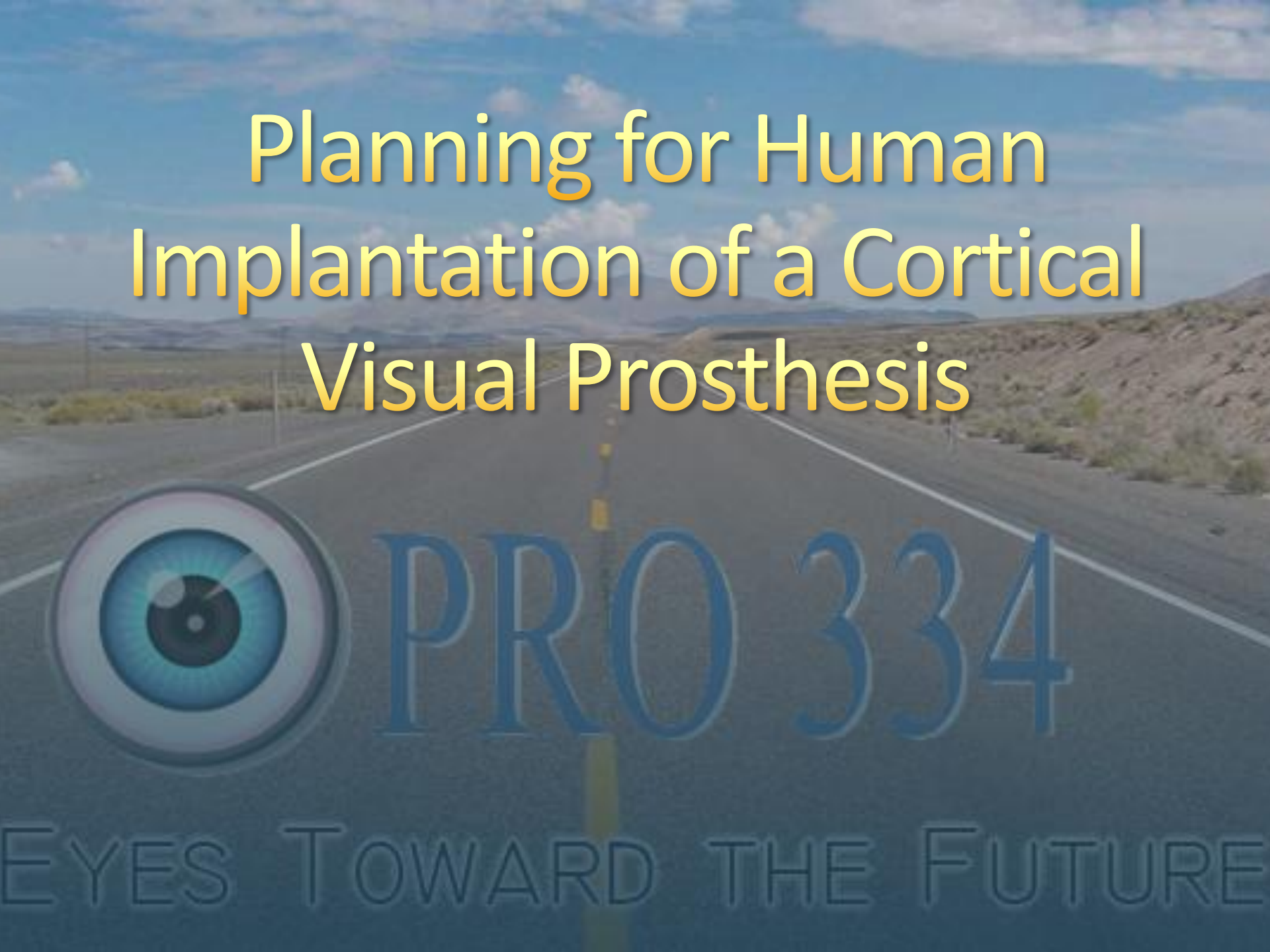
Planning for Human Implantation of a Cortical Visual Prosthesis



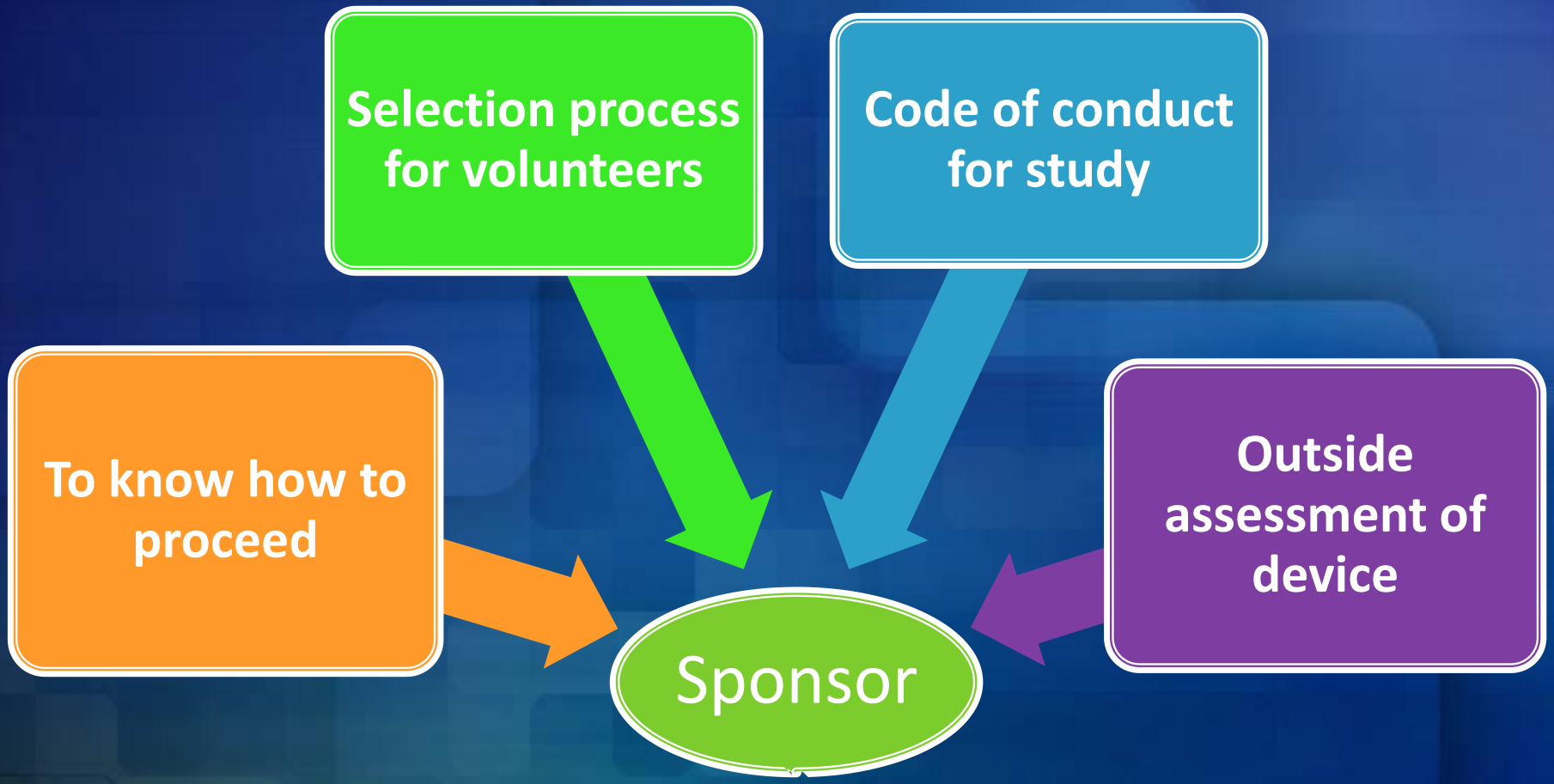
Background

Intra-cortical Visual Prosthesis Team of IIT

- Development of technology
- Safety and Functional Testing
- Proto-typing
- Benefit persons with blindness

http://neural.iit.edu/visualprosthesis2.htm

Needs of the Sponsor



Goals of the Project

To create a comprehensive framework for the selection of volunteers

To assess the current state of the proposed technology and raise concerns that would better prepare it for human implantation

To assemble a report detailing suggestions and concerns to our sponsor

Organization of the Team

Team Management

- Team building and brainstorming
- Team charter
- Frequent goal reassessments
- Converging polar teams into a unified group

Our Research

- Objective based research
  - Brainstorming
  - Discussion
- Considered Codes of Ethics from various disciplines
- Trips to the Lighthouse
- Interviews with Experts
  - Dr. P. Troyk, PhD – Director of Neural Engineering Program at IIT
  - Dr. M. Davis, PhD – Associate Director CSEP
  - Dr. L. Towle, PhD – Associate Professor at U of C
  - D. Weber – Legal Expert in Patent and Liability Law and Former Madison County Circuit Judge

Recommendations Team

Researched FDA approval guidelines

Assess sponsor's device (safety and functionality)

Researched and extrapolated from similar devices

- **Compiled list of technical issues**
- **Asked sponsor if they addressed these issues**

Volunteer Selection Team

Split into three focus groups

- Physiological
- Psychological
- Ethical/Social

Brainstormed questions

Researched and discussed solutions

Cohesion


Sub-team presentations to entire team
Received feedback; gaps in our research were discovered and rectified
Compiled an outline for the report to the sponsor

Report to the Sponsor

Risk Analysis

- Have the potential harms been identified and safeguards put in place?
  - Sponsor has not done formalized risk analysis
- Our conclusion
  - Formalized risk analysis early on
  - Should be documented throughout process
  - Required by FDA
- Discussion
  - Importance of formality

Withdrawal of Consent

- Should the volunteer be able to withdraw their consent?
  - Cost of time and equipment
- Our conclusion
  - Volunteer should have right to withdraw
  - Protocol required for withdrawal
    - Sponsor retains the external device
    - Backup technical safeguards
    - Compensated up to time of withdrawal
- Discussion
  - Legal actions
  - Humanity

Education for Informed Consent

- How do we ensure that the volunteers' consent is informed?
  - Ethical and legal requirement
  - Education vs. superficial lecture
- Our conclusion
  - Repeated information sessions
  - Take home reference
  - Oral exam (interview)
  - Involving friends and family
- Discussion
  - Is it too much?
  - Volunteer's feigning understanding

Brain Plasticity

- Can the device cause non-visual perceptions and should it factor in volunteer selection?
  - Persons with blindness recruit their visual cortex
- Our Conclusion
  - The device would trigger undesired sensations in visual cortexes that have been recruited
  - People with early onset blindness should be excluded
- Discussion
  - Exclusion from future trials

Benefits

Benefits

- Provide unbiased opinions
  - Fresh perspective
  - From the standpoint of the volunteer
- Offer suggestions based on our research
- Broad spectrum of viewpoints

Risks

Risks

- Impact volunteers or researchers negatively
- Divulge sensitive information
- Being affected by bias from sponsor
- Creating an unfocused final report

Challenges

Challenges

- Highly technical subject matter
- Combining two teams
- Properly allocating available time
- Drawing parallels between our devices and other studies
- The ethics of exclusion criteria

Next Steps

Addressing unanswered questions

Finish the framework for volunteer selection

Identify other possible concerns of the device

Acknowledgments

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- We would also like to acknowledge the Intracortical Visual Prosthesis research team at IIT for their technical support.
- In addition, we would like to thank all the people who were interviewed during the course of this IPRO: Leo Towle, Ph.D., Former Circuit Judge Don Weber, and Mike Davis, Ph.D.

Questions