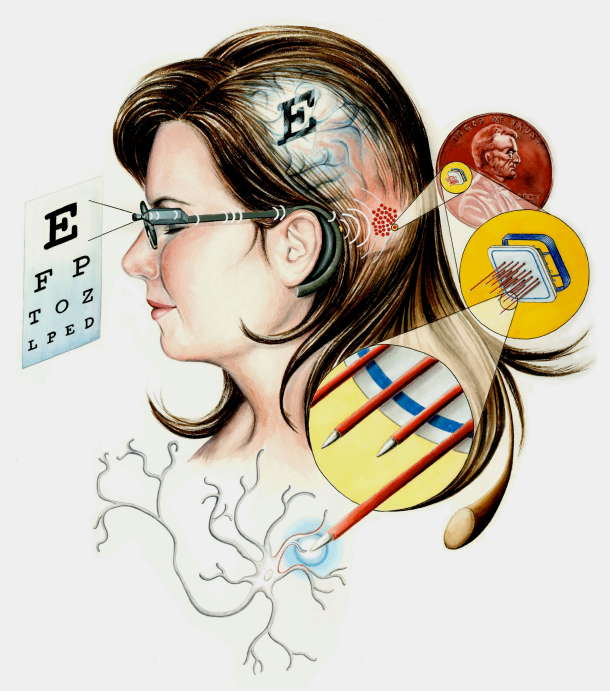
IPRO 306

ILLINOIS INSTITUTE OF TECHNOLOGY

PLANNING FOR HUMAN IMPLANTATION OF A CORTICAL VISUAL PROTHESIS



FINAL REPORT

Fall 2008

I. ABSTRACT

Over the years there has been intensive research on visual prosthesis around the world and significant technological advancements have been made. The Intracortical Visual Prosthesis Team (IVP) at IIT has been researching and developing a procedure as well as a device which will be implanted within the human visual cortex. The device consists of sub-miniature electrodes which will artificially stimulate the visual cortex by introducing electrical currents in to the cortex. The IIT Team has reached a point in their 10 year development process where they would like to proceed with implanting the device in a volunteer in the next few years. Implantation of a device which provides artificial vision is an extraordinarily complex process. In the initial stages the medical and engineering aspects are the most prevalent ones, but as the project moves forward there are some questions that inevitably must be answered or at least considered. These questions deal much less with the technology and much more with the volunteers that will eventually have these complex devices implanted. To try and answer some of these questions, in IPRO 306 we will look into various medical, political, engineering, ethical, media and psychological issues that we believe may become of greater importance as the project progresses into the implementation stage. We will also look into the public relations aspect as well as some political and psychological issues. Based on our research and understanding we will provide several issues that we see as needing to be addressed in the future and recommend possible solutions to them.

II. BACKGROUND

A. This IPRO project is sponsored by the Intracortical Visual Prosthesis Team at IIT, which includes the University of Chicago, Huntington Medical Research Institutes in Pasadena, CA, EIC Laboratories in Norwood, MA, and Micro Probe Inc in Frederick Maryland.

B. The goal of the IPRO team is to create a project road map that will detail the needs and requirements needed to meet the criteria of safety for an implanted prosthesis.

C. Visual prosthetics have been implanted in patients around the world both acutely and chronically. The major types of visual prosthesis involve interfacing at the retina, the optic nerve or in this case the visual cortex. Despite attempts with varying results, a demonstration of a device with the required degree of performance has not yet been made. Although engineering an device such as the intracortical implant would be a great achievement and a great feat of engineering, it will not do much good unless all other political, ethical, moral and medical issues are accounted for, so that it will more easily be accepted by the public with the least, if any, negative impact on the volunteers or society.

D. This IPRO is the first of its kind. No previous IPRO has explored the various moral, ethical, cultural or scientific issues of implanting a human with a visual prosthesis.

E. The IIT Institutional Review Board (IRB) is responsible for reviewing all research involving humans in any way, and deciding whether all involvement with humans is done within strict guidelines, which take into account ethnical, medical, moral and cultural issues. Before any such testing may be done the IRB must approve it. We will review the ethical, medical, cultural, and moral issues and provide our own opinion on whether this device is ready for human implantation, and what may be some possible issues that can arise as the project moves into the implantation stage.

III. OBJECTIVES

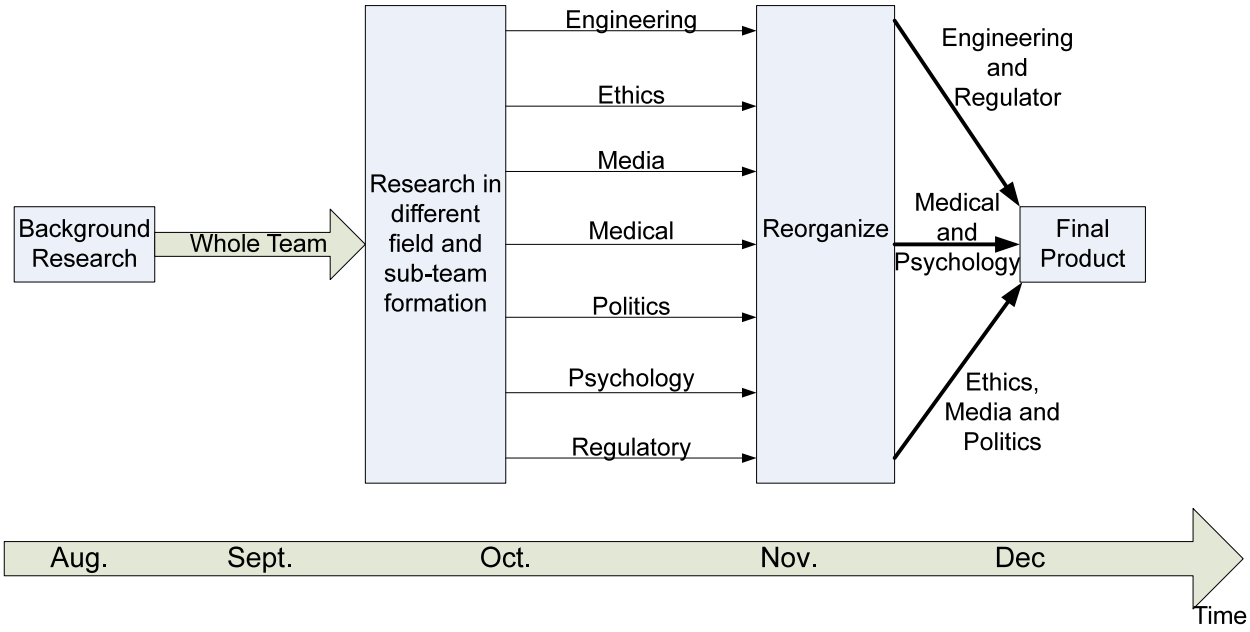
• Review available literature on visual prosthetics, focusing on intracortical, and make an assessment on the status of this technology.

• Explore 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.

IV. METHODOLOGY

A. Team structure: The team was broken down into smaller subteams for enhanced performance and efficient work output. The team structure breakdown is illustrated in the block diagram given below:



B. Problems:

In order to establish a road map toward the implantation of a visual prosthesis, it would be helpful to highlight some important questions that we wish to cover, such as:

- What medical issues can we expect from a brain implant?
- Is the technology advanced enough to successfully install the device?
- What criteria should be considered during the selection process of the volunteers?
- What should the selected volunteers expect?

- How should we educate the public?

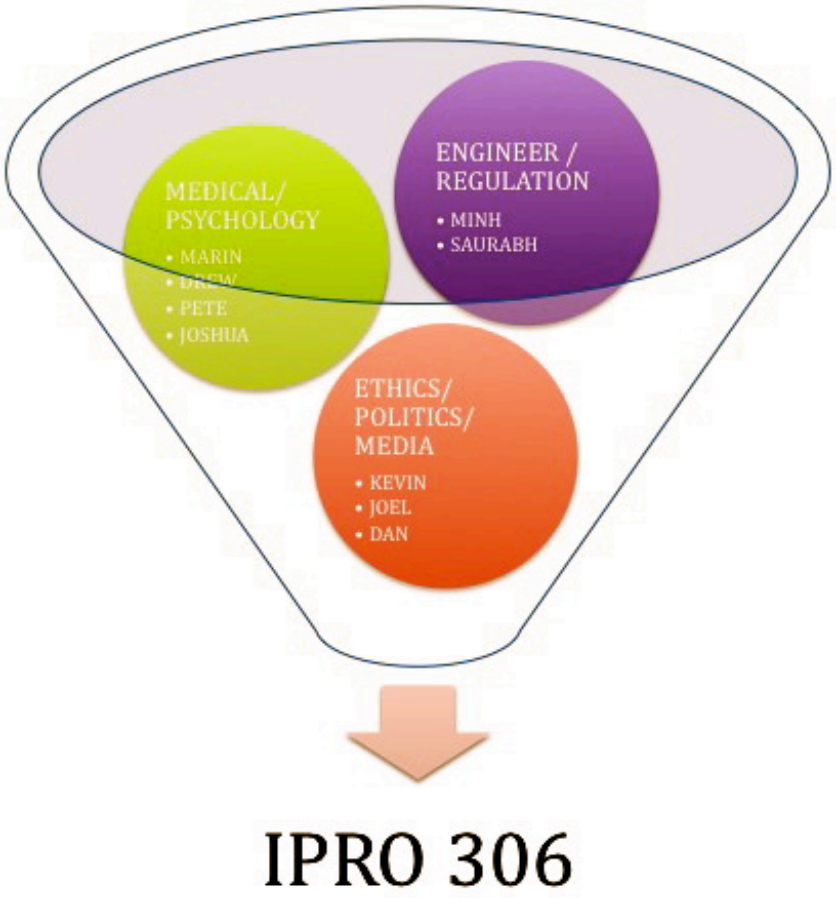
C. Plan of attack:

Since this is the first time we are doing this project and all of the team members come from different backgrounds, we divided the project into two phases. During Phase 1 which is the research phase, all members are expected to raise the knowledge levels on the topic during this phase. We divided into seven sub-teams and assigned tasks to individuals. iGroups online has been organized so team members can upload files to relevant folders and provide a way to often interact with each other so everyone will be at the same level of understanding. The team will also participate in real life interactions (visiting laboratories and the Chicago Lighthouse, interviewing people involved in the project). During Phase 2, we will compile the findings of each subgroup; discuss issues raised along research and start to develop our thoughts on how to attack each issue. In the end of the project we will be able to come up with a list of what are still left to be done and what can be done now for the preparation of the first Human implantation.

D. Possible Outcomes:

By the end of the project, all members are expected to gain knowledge on the topic. Due to the open ended nature of the topic at hand and because of the different factors involved in this evaluation, the team may conclude that the device could or could not safely be tested on human beings. In any case, we will try to provide justifications regarding our final opinion on the subject.

V. TEAM STRUCTURE AND ASSIGNMENTS



VI. BUDGET

The IPRO team is under budget for this semester. There are going to be more expensive in each category besides travel. the last week of the semester as we prepare for IPRO Day, we will have more meetings out side of class and we will need to buy supplies to put together our final report. The Travel category will not change because we do not plan to going to the Chicago Lighthouse for People who are Blind and Visually Impaired. Our Travel expenses came from driving to the Chicago Lighthouse and Parking at the Chicago Lighthouse. Details of the travel category can be seen in Table 2. The out of class meeting expenses came from ordering lunch between focus groups held at the Chicago Lighthouse.

TABLE 2 : TOTAL BUDGET

CATEGORY	REQUESTED	APPROVED	REIMBURSABLE AMOUNT
SUPPLIES	$50	$50	$128.15
TRAVEL	$1,200	$200	$84.30
OUT OF CLASS MEETINGS	$250	$250	$30.29
TOTAL	$1,500	$500	$242.74

VII. RESULT

Appendix A : Final Product (Page 17)

VIII. OBSTACLES

Throughout the semester the team encountered several obstacles while trying to achieve their goals. Time constraints were one of the biggest problems to overcome. Since this is a new IPRO, the team needed to get a lot of background information about the Intracortical Visual Prosthesis Research Project before any work towards our objective could have been made. The team was short on personnel; there were many sub-topics to this IPRO project and not enough people to work on them. Each sub-team encountered their own challenges and obstacles throughout the semester.

Medical Subteam

The biggest obstacle for the Medical team was to find complications that can arise from such an invasive surgical procedure, since there have not been any procedures having over 300 electrodes implanted in the brain, the team had to do extensive research and find creative ways to get the information.

Psychology Subteam

The Psychology team faced many problems. The first problem they encountered was that there was a wide area where they could have done their research; therefore they needed to narrow down their research so it would encompass the Intracortical Visual Prosthesis Project. Another obstacle that this sub-team faced was that the member had conflicting schedules. Working together outside of class time was very difficult and the sub-team needed to rely on sending emails back and forth.

Regulatory/Engineering Subteam

The two biggest problems for the Engineering and Regulatory sub-team was to figure out what institution and federal regulations exist and figure out the status of the engineering of the system. The institution and federal regulations are difficult to find because this is the first time a devices like the wireless Intracortical Visual Prosthesis is

ready for human trials which is a very invasive procedure and the prosthesis is a complicated device. To get an accurate status of the engineering of the device is difficult because there still needs to be many tests done on the devices and having one of the test fail could lead to redesign of the system and more testing. Also the engineers working on the project would have biases about their work and say more is completed then there really is.

Ethics/Media/Politics Subteam

The Ethics, Media and Politics sub-team were three different sub-teams at the beginning. They found that majority of their issues overlapped and decided to work as one team. When they combined, they had problems delegating their tasks because at the beginning the task were being completed in parallel by three different people and after the merger they needed to find a more efficient way of completing their objectives. Another problem the sub-team faced was to narrow down their research. There are many ethical issues to consider when thinking on experimenting on humans. When there are human trials there is a lot of media coverage and politics involved. 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.

IX. RECOMMENDATIONS

In this IPRO we have defined some of the issues that the Intracortical Visual Prosthesis, We believe that the next IPRO should focus on finding solutions to issues discovered. The next IPRO should go more in-depth into the ethical and psychological issues concerned with such a devices. The new IPRO groups should also look to see what improvements are made in all the different areas that were focused on this semester. The focus groups videos should be reviewed to determine what things are important to the customers for this device. For each subteam, we have more detail recommendation listed in Appendix 1 - final result.

X. DISCUSSION

Our group has decided upon several recommendations for the intracortical visual prosthesis (IVP) team to consider while planning for the implantation of the IVP. The engineering team has recommended that mechanical stress, aging temperature, and electrical tests need to be done on the system. The temperature of suggested testing is 605 degrees Celsius because the time frame is reasonable (about 8 months) and it will not cook the modules. The system needs to be connected and run for an extended period of time, about a year, to see if any failures happen. Also, long term structural tests need to be performed to see if the silicone has any cracks in it, especially where the electrodes meet the silicone. The medical team has recommended that the volunteers be from 40 to 75 years of age, in excellent health, have an adventurous attitude, and be strong willed. Also, alternative therapies may be more effective and be less risky than the implantation of the prosthesis. The ethics team has determined that quantitative assessments of the risks and benefits are needed to make an adequate judgment of regarding the justification of the experiment, and to better make the profile of the ideal candidate more precise. Careful inspection of volunteers motives should be done and realistic expectations should be stressed. The media and politics team has stressed the proper release of information to the public and informed consent. The psychology team has recommended that the IVP team prepare for rehabilitation, monitoring of the volunteers mental state, and the potential for device abandonment. Also, the potential for device failure needs to be looked at from a psychological perspective. The regulatory team has come to the conclusion that in order to get approval for the first clinical trial on human subject from the US Food and Drugs Association (FDA) and Illinois Institute of Technology Institutional Review Board (IRB), the device needs to be tested fully as recommended in the engineering part. But in the gap times, tele-conferences and informal meetings should be called with the FDA and IIT IRB. The checklist need to be updated frequent and filled in the details since regulatory could be changed with times. An effective recording system would need to developed as well since it would help to gather all the necessary documents for any regulatory application submission later on.

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Ethics, Media, Politics

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APPENDIX A - FINAL PRODUCT

1. ENGINEERING

The intracortical visual prosthesis system consists of three major components: a real time image-capturing device, processing unit, and the implant modules. An image-capturing device such as a video camera takes an image which is then sent to the processing unit where the image's pixels are mapped to an appropriated phosphene pattern. Afterwards, the data is modulated to a carrier frequency (a channel) using frequency shift keying (FSK) method and it is sent through an inductively-coupled power and data link to the implanted chip. An artist rendering of the system can be seen in Figure 1. There can be up to 63 different chips implanted, which adds up to 1008 different channels.

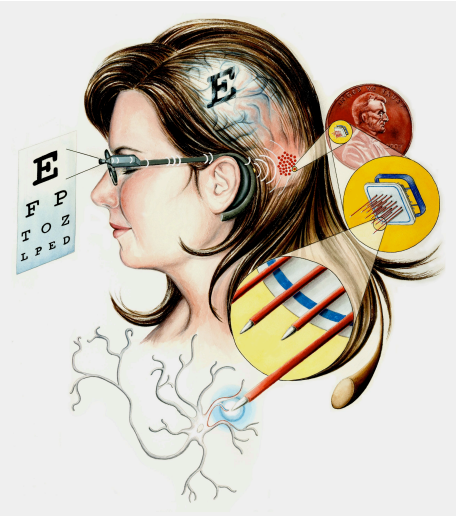


Figure 1: Artist rendering of the visual prosthesis system- this picture shows the camera that captures the image. The signal is from the camera is sent wirelessly form the antenna to the modules in the visual cortex. When the modules gets stimulated, the image that is captured from the camera is perceived by the person.

The most complicated part of the system is the implant chip and it needs to be tested rigorously because modifications cannot be made after the chip in implanted into the volunteer. The power supply and the data for the chip come from the inductively coupled link. The power signal goes to the regulator and the data signal goes to the FSK demodulator. From the demodulator, the data is decoded and interpreted by the finite state machine and the appropriate parameters are set according to the command. A block diagram of the chip can be seen in figure 2 and the output stimulation pulse in figure 3.

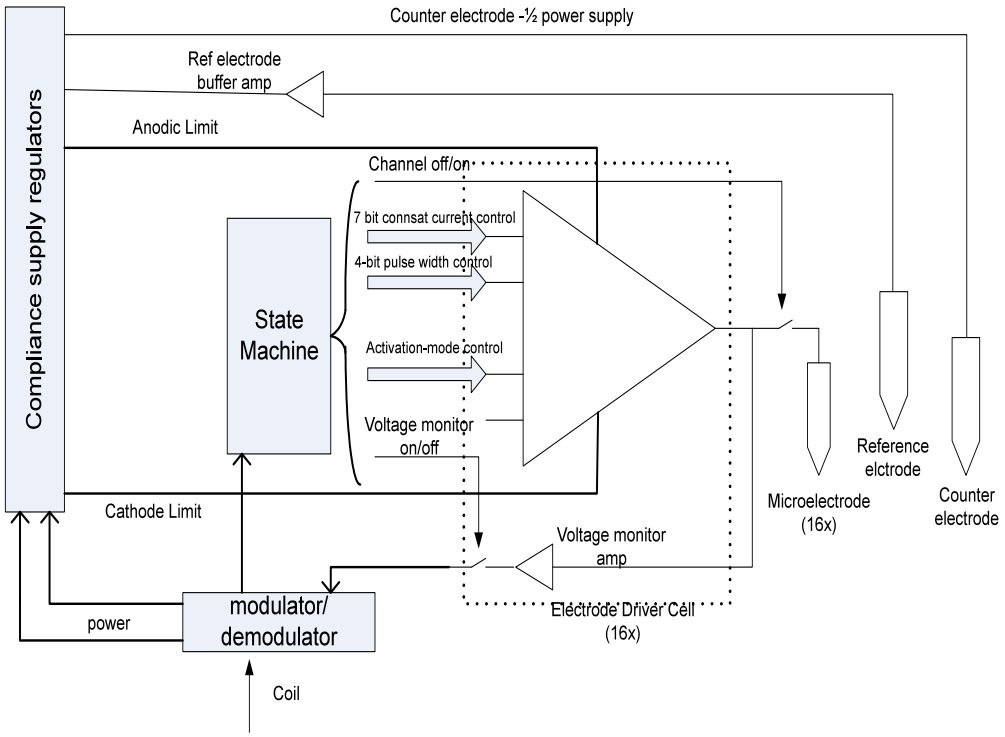


Figure 2 Implant chip block diagram – in this figure one can see the signal flow through the implant chip after it is transmitted from the outside coil. First the power and data are separated. The power signal goes to the compliance supply regulators. The finite state machine decodes the data and depending on the code the appropriate parameters are set for each electrode

Figure 3 shows the current wave form of the stimulation pulse. The amplitude and width parameters of the pulse can be controlled.

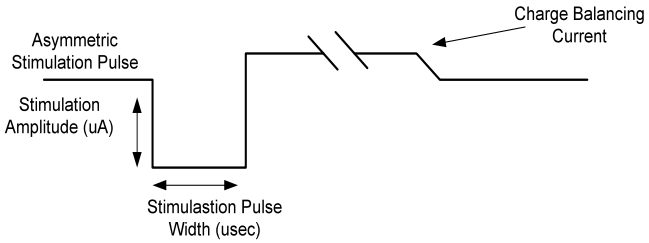


Figure 3 Stimulations Pulse

1a. Status of the device

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 without any problems because after implantation no modifications can be made. There are four major parts to the implant module: the silicon die, the electrode array, the coil and the encapsulation material. The silicon die has been tested electrically to determine the functionality of the chip. The wired and wireless version of the chip works correctly. The test was done by sending an input command and observing the output waveform. There needs to be minor modifications made to the chip such as making the bond pads for the coil larger, but this modification will not have any effect on the operations of the chip.

The wireless version of the chip was tested with the old version of the coil. There needs to be a new coil design due to recent animal testing results. A monkey was implanted with the modules for four years, when the researchers went to examine the implants, they discovered that the brain was compressed at the site of the module. To minimize the compression of the brain, the coil needs to be on the parameter of the silicone die instead of being on the top. The new coil still needs to be designed and tested.

There has been extensive research on the electrodes. The electrodes are made of iridium, a very stable metal. The electrodes are covered with parylene, so gases will not form when stimulating. Parylene is very stable and reproducible. If the coating fails, the

metal will be in direct contact with the fluids in the brain and may cause gases to form. The coating fails when the charge per pulse exceeds a certain threshold. To protect the electrodes, the charge per pulse should not exceed 6nC. The 6nC value was determined by experiments carried out at the Illinois Institute of Technology and the University of Chicago. To protect the neuron, the number of pulse per unit time is important but this value has not been determined. There has been an experiment done on cats, where the cat was stimulated with 50 Hz pulse trains for four months at eight hours per day. The results from the experiments showed that 50 Hz was not a safe stimulation rate because there was neuron damage 100um away from the electrode. The safe frequency still needs to be determined.

The module is going to have 18 different electrodes, 16 of the electrodes are dedicated to the 16 different channels on the chip while the other two electrodes are for the counter and reference voltage. The whole electrode assembly is called the electrode array. The silicon die is attached to the top of the electrode array. The electrode arrays are fully designed and are currently being built. The encapsulation material the researchers would like to use is an industrial grade silicone. The silicone protects the silicon die after an accelerated age test was done. There was no evidence of corrosion on the die. The durations of the tests were not known so the tests need to be performed again. Each batch needs to have a toxicology test done to make sure the silicone is safe for human implantation.

There have been a prototype made of the processing unit and a camera as the image-capturing device. There have been strategies developed on how to map the signals from the camera to the implant chips, but the strategy has not been tested on the whole system.

1b.Goals of the Prosthesis Research Group

The short-term engineering goal of the research group is to have the wireless link working with all the modules in the system. The visual prosthesis researchers need to redesign the coil on the modules and after this is done, they should test their design to see if the wireless telemetry and the reverse telemetry are functional. The long-term goals of

the group are to have a final design of the system completed within three months and be ready for implantation within two years. The final system needs be to designed, assembled, and tested within that time frame.

1c.Design/Testing

Accelerated Testing

Accelerated age testing needs to be conducted on the modules that are being implanted. In an article by Karl J. Hemmerich on accelerated age testing describes "the simplified protocol (the "10-Degree rule")." The rule states that the rate of chemical reaction will increase by a factor of Q10 (reaction-rate coefficient) for every 10oC increase in temperature. The typical Q10 value for medical polymers is 2, this means that the reaction rate doubles with a 10oC increase in temperature1.

A good temperature to use would be what would be to use 650C because it will not cook the modules and the time frame to do the test is reasonable.

Electrical tests needs to be done with the whole system and the system performance needs to be looked at closely. This test would let the researchers know if all the modules are working and if the output corresponds to the input commands. This experiment will be difficult to set up because there will be hundreds of wires connected to the electrodes to measure the output. The experiment should be done at least for a year to see if any chips fail over time.

Long-term structural stress tests need to be performed on the module to determine the silicone will not have any cracks in it. One area of concern is where the electrodes meet the silicone. Silicone does not bond to many surfaces and if there is a gap between the electrodes it can grow over time and allow fluids to get inside the module. Changing the temperature rapidly by having the modules sit in ice water and then move them into boiling water for 20 times a day is one way the structural failures can be accelerated.

1d.Modification

There are modifications still being made to the design. The coil that is on the implanted module needs to be redesigned and tested to minimize the height of the module and the amount of brain compression. Recent animal testing results show that the animal's brain was compressed were the modules where placed. On the chip, the pads where the coil needs to connect to needs to be made larger. The larger surface area for the coil would make the bonds stronger.

1e. Obstacles

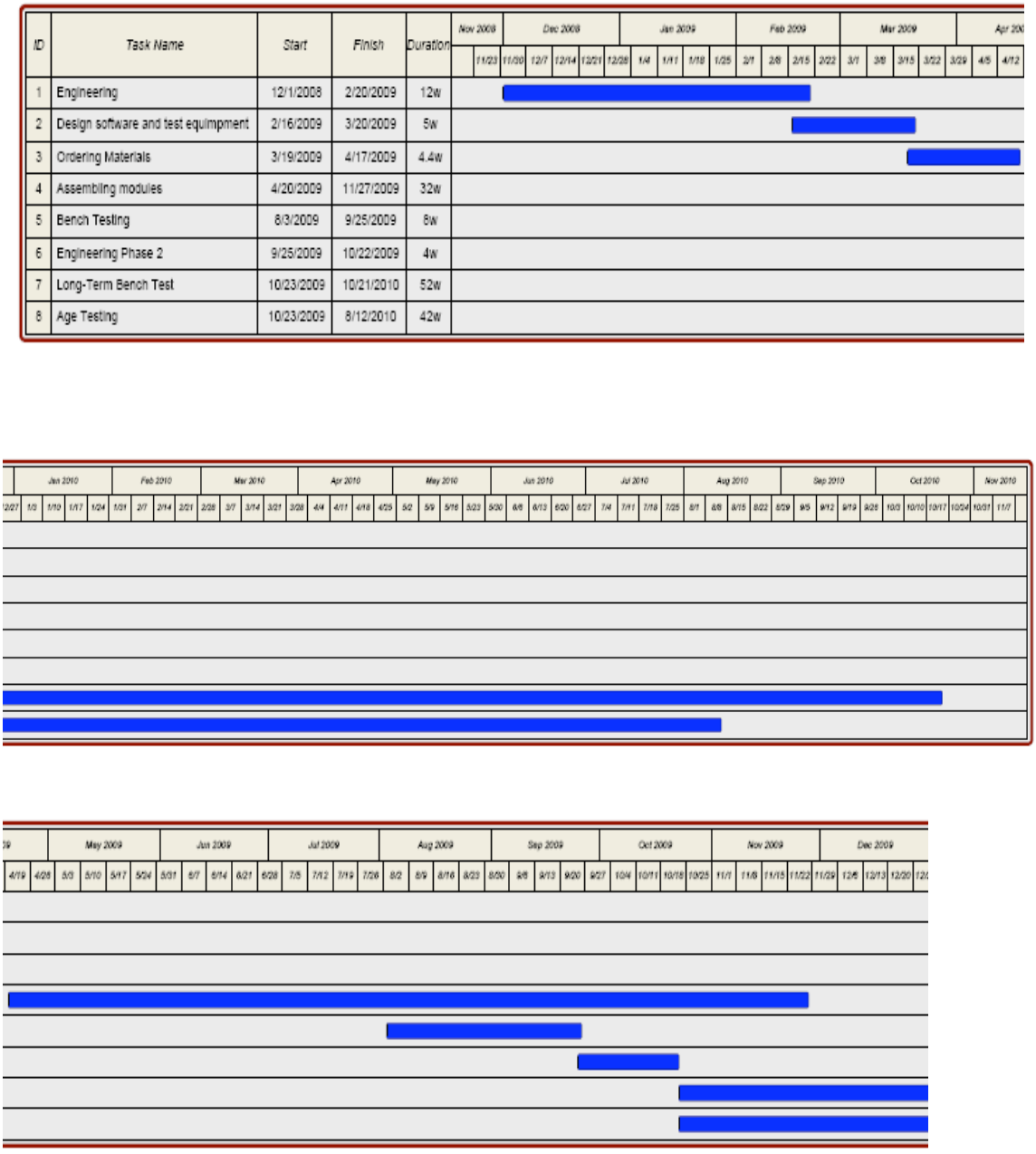
For the team to meet their two year projected time frame to have the engineering completed, they are going to face many challenges. The system has to work the first time it is tested and there cannot be any major modifications made. If there are modifications made the testing would have to start from the beginning and waste a lot of time. The Obstacle here is that in engineering things usually do not work when being tested for the first time. That means the engineering is going to go through cycles of design, assembly, testing and modification, until the final product is bug free.

The Visual prosthesis team needs to figure out a save simulations rate (pulses per second). An attempt was done to figure out the rate but from the experiment it was determined that a stimulation rate of 50 Hz is not safe because there was neuron damage 100um from where the electrodes were implanted. Further experiment needs to be performed to figure out the safe stimulate rate. The researchers believe the duty cycle (percent that the pulse in on in a cycle) might need to be changed.

1f.Timeline

There are many important steps needed to be taking before the engineering can be completed. First the engineers need to have a compete design which should take about three months. Then testing equipment and software needs to be designed to test each individual module before implantations. Someone needs to layout circuit board and order parts. After some modules are assembled there should be a couple of months for testing and redesign before the final design is set. Assemble of the modules will take 8

months time. A person can assemble 2 modules per week. That means that to assemble 50 modules would take about 4 months. After the first 50 modules are assembled and tested, they can be used fro the long-term test and the age test. At the same time the tests are being conducted the assembler can assemble more modules that would be used for implantations.



ID	Task Name	Start	Finish	Duration
1	Engineering	12/1/2008	2/20/2009	12w
2	Design software and test equimpment	2/16/2009	3/20/2009	5w
3	Ordering Materials	3/19/2009	4/17/2009	4.4w
4	Assembling modules	4/20/2009	11/27/2009	32w
5	Bench Testing	8/3/2009	9/25/2009	8w
6	Engineering Phase 2	9/25/2009	10/22/2009	4w
7	Long-Term Bench Test	10/23/2009	10/21/2010	52w
8	Age Testing	10/23/2009	8/12/2010	42w

Figure 4: Gantt chart for engineering process.

2. REGULATORY

Since our Intracortical Visual Prothesis (IVP) device is engineered to restore Vision - one of the human body's natural functions, it is considered a Medical Device and has to be regulated under the US Food & Drug Administration (FDA). The Investigational Device Exemptions (IDE) regulation (21 CFR 812) describes 3 types of device studies: Significant Risk Device (SR), Nonsignificant Risk Device (NSR) & exempt studies. 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 regulation 21 CFR 812.3(m):

The device:

• Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

• Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

• Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

• Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

1a. Regulation Checklist/Timeline

1a	IDE to IIT -IRB	• Submit an IIT IRB application (included an original & 12 copies of the application to the office of research compliance & proposal development. • What information is needed in IIT IRB Application: A. Essential Data B. Objective of Research C. Protocols D. Selection of subjects E. Deception F. Confidentiality of data G. Informed Consent H. Risks I. Benefits J. Certification - signed and dated • Notes: IRB approval is given one / year, if doing multi year project, must submit application again.	• By 5:00 pm the date at which are 2 weeks prior to the schedule IRB review meeting. • No later than 45 days prior to the first clinical trial.

1b	IDE to get FDA approval	• Since our device is class III device, IDE must be approved by FDA as well. • Pre IFE : Informal and formal guidance meetings, it 's also encouraged to submit pre IDE while preparing IDE submission because we might need FDA guidance on troublesome parts of IDE application (Protocols design etc..) • Send IDE application to Center for Devices & Radiological Health, Food & Drug administration (CDRH) Address: Document Mail center (HFR -401) Center for Devices & Radiological Health, Food & Drug administration, 92000 Corporated Blvd, Rockville, MD 20850 Can't start the clinical trial until get approved by FDA Must submit 3 copies of signed " Application for an IDE" together with accompanied materials.	• For a pre IDE, response will be given within 60 days of period. • FDA will provide a written determination latest 30 days after receiving an IDE.

2	Clinical trial	Must record every single step, procedure, must have informed consent from every subject. Clinical Data: Enrolment, Visual Performance Assessment, Life Activities, Endpoints, Safety and Effectiveness Preclinical Data Device descriptions- Design specifications: Device, inserters, Video processing unites, cameras. Pictorial representations	1 year?
3	Pre Market Approvals (PMA)	- Requires submission of significant additional documentation in evaluating a PMA to ensure safety and effectiveness and annual reports even after PMA is granted	6 months - 1 year
		- PMA approval process: FDA 's CDRH will evaluate along with outside expertise(advisory committees) , they have the checklist for filling decision for PMA.	

4	Post Approval	+ Annual report summarize any unpublished clinical datas or laboratory data, published literature + Example :Test Evaluations Timetable Patient Test Evaluations Time Table -Interval: Test every 3 months -Follow up: minimum of 3 yrs is suggested -Critical: Document performance and variability: -Sample patient's visual performance multiple times both pre- and post-implantations + PMA supplement whenever changes are made to the device + Aware of restriction on PMA approval on sales and distribution.	

1b. Recommendations:

IIT IVP team should conduct informal meeting pre Investigational Device Exemption (IDE) meetings / tele-conferences with IIT Institutional Review Board (IRB) and the Food and Drugs Administration (FDA).It 's also essential to have a system to record all pre/post clinical data, consent forms & other related changes, documents. IIT - IVP team needs proper regulatory infrastructure.

3. MEDICAL

3a. Surgery/Risks

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.

In simplified terms, the major steps of the operation involve making incisions in the scalp where access to the brain will be needed. The size of the tissue to be removed will be in the range of a couple of inches in diameter. Once the scalp tissue is cut it is folded back to gain access to the skull. To remove the skull, several small holes are drilled with a high-speed drill into the skull at the outline of the area that is to be removed, and then a fine wire saw is used to cut between the holes that were previously drilled. The released bone is then removed and access to the underlying tissue is obtained. At this point he actual implanting of the device takes place. The electrode arrays are put into position using a high-speed insertion too, which avoids damage to the brain tissue by inserting the electrodes at a high speed. The tip of the electrodes has been designed such that when it is inserted into the brain it does not puncture any blood vessels. This is needed because the brain has a very rich supply of blood vessels and puncturing them would lead to bleeding within the brain which is life threatening. The design of the tip of the electrodes is analogous to the shape of a submarine bow, which is blunt instead of sharp, which causes the medium it moves through to be pushed aside instead of being punctured as it would be with a pointed tip. Once the insertion is completed the bone which was removed is placed back and is secured with wire. The scalp tissue is then put into its original position and is sutured in place. This last step may seem as the most simple one, but it is really is not, because the scalp tissue has many blood vessels running through it which must be reconnected or else the tissue which was cut will not survive.

The major risks that exist with most surgeries are infection and bleeding which in most cases are not life threatening but when they are located within the brain they can be extremely life threatening. Uncontrolled or unexpected bleeding during other surgeries is a major problem, but in brain surgery it is a critical problem which is life threatening or may cause brain damage. The uncontrolled loss of blood referred to as hemorrhaging, and when in the context of blood leaving the blood vessels and flowing into the brain is referred as Cerebral Hemorrhaging. The reason why this is more severe with brain surgery is twofold; for one blood is toxic to the brain, and the other is that the part of the brain that will usually receive its blood supply from the ruptured vessel will no longer have a blood supply, and this is referred to as a stroke. Both of these outcomes can be life threatening if not treated rapidly. During this implantation procedure there is a risk that the protective membrane around the brain may become infected which if untreated results in Meningitis. The challenging part with fighting infection is that the surgeons will not know if infection has occurred during the surgery, the soonest they will know is as the patient starts to recover. For this reason patients are preemptively prescribed medication which would help fight off infection if it were to occur. Another potential risk is the occurrence of seizures which may occur due to the surgery or the device itself. The seizures caused by the surgery are common among all craniotomies and is not specific to the implantation of this device. In this case medications to suppress the seizures are usually prescribed. The device itself can potentially also cause seizures when turned on. It is believed that certain waves or patterns produced by the device may induce seizures. The latter cause of seizures is not a major issue because once the particular waves or patterns are identified the device can be reprogrammed to avoid repeating them. Because the surgery has to do with direct contact to the brain, there is always the risk of brain damage or loss of certain brain functions to an unknown extent. With careful planning, patience and an experienced neurosurgeon, the risk of damage to the brain by direct contact is very small.

An issue related to the device itself is its longevity. This device will stay implanted in the volunteer for the rest of their lifetime, therefore it needs to be designed and tested to be able to do that. Unfortunately, there have been no previous implantations of this de-

vice in humans so the actual affect it will have on the body, or the affect the body will have on it is not completely known. There is the risk that with time the seals on the device might fail, due to corrosion, and the fluid might flow into the device causing unexpected operation which could potentially harm the person. Although this device has been implanted in animals for testing and studying its safety, the trials have not lasted as long as these devices are expected to remain in a human volunteer. It is believe that the current design of the implant is such that this will not happen, however with the lack of actual long term data no one can be completely sure.

The likelihood of any of these complications occurring with a particular patient cannot be predicted. All of these risks listed are possible, however may be unlikely, and depend on the health of the patient, how their body responds to the changes, and how well the procedure is performed.

3b.Medical Obstacles

One of the major obstacles in creating a successful intracortical visual prosthesis such that will integrate seamlessly with the brain is that there are no previous developments to build on because such a device never existed before. This is a new field of prosthetic devices, with very little previous research, which requires most of research and development to be started from almost nothing. Even so, there are some previous devices, although not the same as this one, that have been implanted in individuals which have provide information that can prove to be invaluable to the development of this device. Most of the information that will apply to this device will come from studies on the visual system of the human body, and any information concerning functionality or the technical aspect will mostly be inferred from implanted devices, which may be of a completely different nature. The information from other implantable device will be able to contribute somewhat to address the biocompatibility concerns, because a major issue here is how the body will interact with this device, will it accept it or will complications develop due to its presence.

The expected gain in vision range from no affect at all, to at best making an individual that is completely blind have an increase in vision to the level that they can be classified

as legally blind. The major reason for these expectations is that it is not know what will happen. Although these expectations may not look impressive they certainly are, and on the contrary, they would be remarkable. To be able to bring an individual from total blindness into legal blindness classification would be a great progress in the right direction, and to be able to give an individual some of their independence back will be no less than remarkable. On the other hand, even if the results are on the worst side of the expectations and the individual has no improvement in vision, the project itself would still make a great contribution to the field, because the device and the medical implications will be better understood and later projects will have a better chance at being successful.

4. PSYCHOLOGY

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?

- Negative Consequences of Vision Loss:

- Impact on others:

  - measured by: ability to contribute socially, economically, to family issues (providing VS being provided for)

- Anxiety and depression:

  - measured by: prevalence and incidence given target populations (more common among elderly)

- Limited participation/social isolation:

  - measured by: decrease in likelihood to engage in social/family life, participation in activities, limited access/interactions can lead to feelings of isolation

- Reduced earning capacity:

  - measured by occupational restrictions/limitations/rejection/relinquishment

- Difficulties with daily activities:

  - measured by: lifestyle, environment, and social support, as well as the severity of their vision loss, age of onset

- Information overload:

  - Vision requires vast amounts of information processing

- In subjects who must work at seeing, can lead to exhaustion, stress, anxiety, and other ill effects
- Contributes to higher rate of depression

- Positive Consequences of Vision Restoration:

♣ Greater social inclusion and participation:

- Measured by: restoring confidence, ability to produce/interact/become more involved

♣ Engagement in productive activities:

- Contributions (comparatively) that were once limited might increase as opportunities become more available

♣ Increased self-esteem:

- Self-efficacy improved; respect from others; acknowledgment

♣ Improved communication and relationships:

- Measured by: being more trusting of others, stronger social relationships

♣ Wider impact:

- Groups, community (blind), procedures, funding, attention

What barriers exist that may prevent potential subjects from wanting to be involved in the experimental phase of this device?

- Financial Costs
- Irreversibility of Procedure
- Potential for Device Failure

- Determining if subject is psychologically/emotionally ready to use device
- Side Effects
- Lack of Information (or understanding) about Device
- Subjects may look to alternative methods:
  - ♣ Gene therapy
  - ♣ Other prosthetic devices (ex: retinal)
  - ♣ Other assistive technologies (ex: canes, GPS navigation devices, existing/developing technologies)
- Psychological Evaluations and Testing for Approval of Subjects
  - ♣ May also be opposed to these methods
- Time and Commitment to the Experimental Regime
  - ♣ May be too large a responsibility for some potential subjects

Rehabilitation will most likely be necessary for those who participate in this experiment.

What types of rehabilitation may be offered?

- Vocational Rehabilitation
- Occupational Therapy
- Physical Therapy
- Rehabilitation Counseling
- Disability Management
- Support Groups

♣ Positive: provide access to other persons with similar diagnoses, issues, needs

♣ Negative: impede progress by opposing therapeutic goals

What might the goals of rehabilitation be in order to increase the effectiveness of this device and of the individual who wishes to use it?

o To determine under what circumstances provisions or services may not be granted

o Having professionals learn device/engineering

♣ Determining who advises them, instructs them

o Achieving greater independence

o Integrate rehabilitation engineering behind this device with the professional community that might be expected to provide services to persons with this prosthesis

♣ For example:

• Medical doctors providing services to individuals who may have this prosthesis but who are unfamiliar with this device will need to be well-informed about the device, its possible side effects, etc

• Preferably this should be handled at the professional level, as directly as possible

o Provide information or education for families of subjects

o Learning new ways to perform functions of daily living

o Evaluate effectiveness of existing rehabilitation strategies and programs to determine and or predict what might be beneficial according to this particular design

o Assess rehabilitative services' impact on task performance, psychosocial and psychological factors, and quality of life

Using what we know from previous models of assistive technologies (specifically prosthetic devices such as cochlear implants and retinal prostheses) there has been a need to provide subjects with thorough information, advice, and guidance so that they can maximize the efficacy of their device and adapt to using it in their environment. What can we expect to arise given the nature of what is at stake psychologically for the individual participating in this experiment?

o Subjects may abandon the device under certain conditions:

♣ For example:

- If it is inconsistent (functionally)
- If it performs to a lesser degree than expected
- If it causes problems for vision rather than helping it
- If it causes a degree of undesirable stress
- If it takes too much adjustment to use effectively (personal and environmental)
- If there are negative reactions from within the community
- Due to self-image issues (acclimatization: incorporation of device into body-image)

o First impressions, primary to the function (utility) of device

- Due to negative external beliefs: initial focus (from others) is on assistive device (people see the device first and foremost, not the person)

o Subjects may gradually become dependent on sight

♣ For example:

- If this prosthesis benefits vision, one might neglect his or her other senses which had been previously better developed due to condition (blindness)

o Subjects may not properly use the device unless advised and instructed on how to do so by:

♣ Professionals, trained and instructed

♣ Rehabilitation Engineers behind device

♣ Medical supervisors, those monitoring subjects

Age is an important factor, and rehabilitation will need to address certain special considerations for adults and persons 65+, who constitute more than 2/3 of the population with visual impairments

o Prepare for an estimate of twice this many people coming into population by 2030

o Rehabilitation issues with this population:

♣ Depression

•Very high rate of depression among subjects who regain sight

•Inordinate expectations of sight reacquisition (pollution, litter, cracked paint, etc. are often surprising)

•Loss of disability pay

•Length and difficulty of rehabilitation

♣ Decrease in independence

♣ Increased risk of falls and fractures

♣ Isolation, availability of resources (limited access)

Crashing Through: by Robert Kurson

Michael May:

- Blinded at age 3

- Lived 42 years without sight, until he was 45 and received stem-cell transplant surgery

- He was aware of the risks (for the type of surgery he received, not the Implant), including death through complications and cancer from the immuno-suppressants.

- Fewer than 20 cases in all of history that have documented sight reacquisition for a subject blind from such a young age.

- May didn't need this treatment; was confident, successful, and it was difficult for him to consider the need to do this treatment given his successes.

- May ended with a "hybrid of vision": some parts of vision work, whereas others barely worked at all. Motion and color (for example) were successes for Michael May, however, human facial recognition was quite difficult (facial expressions); depth perception was nearly impossible; he had difficulty identifying common objects; these were all 'brain issues' and due to the way his brain interpreted the information, not 'eye-related issues'.

- Everything he saw had to be discerned, thought about, processed: stimulation overload becomes a type of burden. Contributed to exhaustion and depression.

- "I didn't do this to see, I did this to see what seeing was" – Michael May. He had the surgery out of curiosity, not from expectations that his life would be better.

- There were no remnants of visual abilities (like depth perception) when he went 40+ years into blindness, thus he essentially had to discover these processes for the first time upon sight reacquisition. Possible subjects for the implant discussed in this IPRO will have adult onset blindness, hopefully minimizing this difficulty.

5. ETHICS/POLITICS/MEDIA

5a.Goals and Obstacles

The goal of the ethical and media/politics groups is to assess the ethical, political and public-related issues that are raised by the prospect of implanting an intracortical visual prosthesis in a human being. One major obstacle encountered has been the scarcity of information related to the topic discussed; even though similar experiments had been done, their results were either outdated, or the experiments were not very successful.

The Problem of Human Experimentation and Ethical Principles:

In the development of new medical devices, drugs, and techniques, one of the most difficult challenges for scientists is determining the safety and effectiveness of medical products on the human beings. One way to overcome the challenge has been to use people as experimental subjects; since they are the ultimate receivers of the technology being developed, it sounds logical to test the products of medical research. However, such a way of thinking ignores one of the highest moral obligations imposed by society on each of us: our regular activities should not harm or threaten human life. By using methods and products previously untested on human beings, we risk defaulting to our obligations of protecting human life; on the other hand, experimental trials allow us to know more about the product being tested and to open the doors to new improvement options, which in turn gives more opportunities for people to improve their life. The inquiry here becomes how do we balance our need to protect human life against our need to improve our standard of living? In other words, what are the steps to take in order to conduct ethical human experimentation?

The atrocities of World War II (during which numerous prisoners were unwillingly used as trial subjects) and the succeeding Nuremberg trials, as well as the Tuskegee Syphilis Study (during which 400 African Americans were used as subjects without their knowledge or consent) laid the framework of recommendations that any clinical trial needs to follow in order to be considered ethical. Those recommendations are embodied in documents such as the Belmont Report, the Nuremberg code, and the Helsinki Declaration. In our discussion on the ethical issues related to the implantation of a intracortical

visual prosthesis, we will consider the principles outlined in the Belmont Report. The document states that there are "three basic principles, among those generally accepted in our cultural tradition, [that] are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice:"

Respect of Persons:

This principle has two aspects which underline the necessity to obtain the voluntary agreement of the subject; it also mentions the kind of relationship that should exist between the researchers and the volunteers:

- Humans should be treated as autonomous agents: people should be regarded as individuals capable of independently choosing their goals and capable of acting towards those goals. Thus, respecting their autonomy means giving weight to subjects' opinions without interfering with their decisions unless the said decisions are harmful to others.

- People with limited autonomy are entitled to protection: in cases where the self-determination of a person is limited (by age or physical or mental condition), it is essential to make sure that such their participation is not the result of some sort of exploitation of their condition.

5b. Beneficence

This principle emphasizes the need to protect the welfare of the subjects. In order to respect the principle of beneficence, researchers have the obligation to conduct their experiment with the least amount of risks and the maximum amount of benefits. Here, the idea of benefits extends to the researchers and, in general, society. Therefore, clinical trials with significant benefits for the research team and few to no immediate benefits for the volunteers could be justified under the principle of beneficence, provided that other factors are considered.

Justice

The idea of justice refers to the fair distribution of benefits and burdens of experiments among the population (of volunteers). Historically, injustice in scientific research has been manifested through the selection of subjects (who were usually among the poor, prisoners, and minorities) and the social status of the beneficiaries of new medical advances (financially and politically powerful social classes). The principle of justice specifically targets the volunteer selection process and demands "both that [research leading to new therapeutic devices and procedures] not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research" (Belmont Report). With the three principles in mind, it becomes important to know how to apply them to the implantation of the visual prosthesis.

The Intracortical Visual Prosthesis: Ethical Considerations

During the semester, we focused on the ethical issues to consider in order to execute the first implantation of a intracortical visual prosthesis in a human being. In order to mention all the relevant issues, an approach similar to that prescribed by the Belmont Report was adopted: the document suggests that to give an ethical characteristic in a human experimentation project, it is essential to establish an informed consent, evaluate all the possible risks and anticipated benefits of the experiment, and specify the selection criteria of the volunteers.

Informed Consent

An informed consent form is a document whereby a person can be said to have given their consent based upon a clear understanding and comprehension of the facts and consequences of an action. The consent process usually contains three main elements: information, comprehension, and voluntariness. Sufficient information that should be provided to the participant include the research procedure, the research purpose, risks and anticipated benefits, alternative available procedures, and assuring the participant the opportunity to ask questions and to withdraw from the research study at any time. Consent forms should be written in the second person and the reading level of the text should be non-technical language. The consent form begins with a section that outlines

and explains the study procedure, where it must explain the purpose of the study and describe the procedures to be followed. An estimated amount of time involved in the study should be provided and all procedures that are experimental are identified. The consent form will also have a risk and discomforts section where it lists all the foreseeable risks or discomforts to the participant. The benefits section will state any potential benefits to the participant and if there is no potential direct benefit, that fact should also be stated in this section. The confidentiality section must describe the extent to which confidentiality of participants will be maintained, a list of whom may have access to the participant's records (federal government, etc.) and include UAB IRB. Under the refusal or withdrawal without penalty section of the consent form, it should explain the consequences of a participant's decision to withdraw from the research and include procedures for orderly termination of participation.

The principle of respect for persons require that participants be given the opportunity to choose what shall or shall not happen to them and this element is provided when adequate standards for informed consent are satisfied. The consent form should also specify any costs to the participant that might result from the research and if standard medical care is provided during the study. The consent form muse indicate who will be responsible for payment of study-related injuries and it must indicate whether or not the sponsor will pay for compensation or medical treatment of these injuries. The consent form must also state that any new significant findings developed during the course of the research that may affect the participant's willingness to continue participation will be provided at a timely basis. The last part of the consent form should include contact information made available to participant and have the participant date and sign their consent. The agreement to participate in a study is only a valid and legal consent if it is given voluntarily and requires conditions free of coercion, extortion, and undue influence. Therefore, the consent form must be honest and truthful and provide any information that is relevant to the study so that the participant can make a well-educated decision.

5c. Risks and Benefits

As stated before in the description of the beneficence principle, a project involving human experimentation ought to have tangible benefits, and those benefits should outweigh the risks. In order to evaluate the benefits and hazards, it is important to know their nature and scope. Moreover, the evaluation of an experimentation of this nature ought to include an assessment its justifiability, which should reflect at least five factors:

1. brutal or inhumane treatment of human subjects is never morally justified;

2. risks should be reduced to those necessary to achieve the research objective;

3. review committees should be extraordinarily insistent on the justification of the risk in the event that research involves significant risk of serious impairment (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation);

4. the appropriateness of involving vulnerable populations should be demonstrated if they are considered potential volunteers;

5. relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

Depending on the aspects addressed in the research, different risks related to the implantation of the intracortical visual prosthesis have been identified. Although they have been discussed in other parts of the report, it is worth mentioning that their nature ranges from medical and technical to psychological and political aspects. While psychological concerns focus on how the relationship between the volunteers, their environment, and themselves will change after the implantation, hazards linked to the technical and medical aspects of the implantation are much more immediate since they involve more than minimal risks. For example, the implant is likely to be permanent; in other words, after the implantation procedure is completed, it will be impossible to remove

and modify the device. Therefore, the research team should consider the safest ways to respond to the implications that living with a permanent implant will create.

The scope of the risks involved mostly cover the subject and the family of the subject. Indeed, most of the potential hazards are linked to the device and its operation in the cerebral environment, and we could say that the volunteers would carry a majority of the consequences in the worst-case scenarios. It is important to note, however, that all the risks mentioned so far are of qualitative value. We do not know the probability of their occurrence, which would be crucial to take in account. In fact, the gravity of the risks can be heightened or lessened by acknowledging other factors such as the health status, the age, and medical history of potential volunteers.

For volunteers, the benefits of the experiment appear to be limited by the fact that we cannot predict with certitude whether or not the device will work as expected on a human being. As a matter of fact, the main goal of the first experiment will be to test the safety of the device in the environment it is intended to be. Hence, it is only after the implantation and careful monitoring that it will be possible to determine the improve the device. Nevertheless, it is possible that the volunteers get vision perception, and they may be able use the prosthesis as an additional tool to help them overcome their condition.

For the research team, a successful experiment will allow them to:

I. verify the assumed medical, engineering-related, and psychological risks;

II. get an accurate feedback;

III. use the response to the device in order to determine the functions best fulfilled by the device;

IV. improve the safety and effectiveness of the device;

V. contribute to the general knowledge about the workings of the brain and most importantly, the visual cortex.

Selection Criteria

According to the Belmont Report, the selection process of any experiment should respect the principle of justice, that is, the rewards and burden of the experiment should be shared by the people involved in the research, from the volunteers to the potential beneficiaries. Furthermore, special attention should be given to people who could be considered vulnerable: some examples of groups are minorities, disadvantaged people, and children.

Medical considerations regarding the selection process have been suggested in the medical aspects of the research(IPRO). The most favorable candidates are adults with excellent medical history and acquired blindness. In other words, potential volunteers have to have lost their sight after they were born. Also, potential volunteers should preferably be totally blind: the reason for this is because, as of now, the prosthesis is not believed to be effective enough to be of any use for a legally blind person.

The medical conditions required to volunteer already rule out the possible participation of children. However, it should also be noted that the goal of the experimentation is primarily to evaluate the safety of the device; besides, blindness is not a condition exclusive to children. Therefore, it is unlikely that considering the participation of non-adults for this experiment would seem justifiable under the FDA regulations, as underlined in the regulations regarding the treatment of human subjects.

Another group that we need to consider are impoverished people. Among people living with blindness or vision loss, a large percentage (30% according to the American Foundation for the Blind) are living with an annual income of $20,000 or less, which makes approximately 6 million people. Considering that part of the population is important because in terms of percentage, there are three times more poor people affected by blindness than there are poor people with no significant disabilities or impairment. From an ethical standpoint, involving underprivileged people in research is a complicated idea: they might believe that the experiment is going to improve their condition, and they might be willing to participate in the study without weighing all the possible consequences. Although it is not possible to rule out the participation of underprivi-

leged people, the investigators should be very careful as far the motivations of the potential candidates are concerned; also they should be very clear about the expectations of the team for the volunteers and for the advancement of research itself.

Best method to transmit/release correct information.

Release of correct information about the device to the public is an important issue to consider because it affects the public opinion and knowledge regarding the device. It is important to release honest and correct information and to find different channels to release the information through. Possible ways of releasing information can include, for example, publishing articles in literature journals, which is a great way to share information with professionals in the same field and to discuss the device in an academic environment. Literature journals are often known for their academic integrity and it would be important to be respected and accepted by educated professionals. Conducting public interviews with the media or holding press conferences are a great way to provide insight to the device and getting the word out to the general public. Having an independent committee evaluate the device would be a great way to validate the IIT IVP team's results and receive an objective perspective on the device and its functions. Attending conferences and seminars to share information with the public and illustrate how the device works and the benefits of the device would also be appropriate. After the device has progressed into the human volunteer implantation stage, it would be useful to obtain personal statements from volunteers and receive feedback on their thoughts. Analyzing personal statements from volunteers who are participating in the program is also a great way to understand the opinions and perspectives from individuals who are blind and are living with the device. Personal statements would be a beneficial way to distinguish the difference between personal experience and theoretical experience.

5d. Focus Groups

Currently, there are focus groups studying the concerns and thoughts of blind individuals on the intracortical visual prosthesis. The results from focus groups could benefit researchers and future volunteers by providing researchers with insight and valuable feedback. Data will be collected from videotaped and voice recorded interviews with the participants. Depending on the feedback received, the research team can improve or modify their design to meet the needs and concerns of the blind community. From the research obtained from focus groups, the researcher will be made aware of the many issues not limited to the engineering and technology of the device, to develop a better product.

Ethics Education Plan

An important step to the volunteer process is the consent form. At the end of the consent form is a statement stating that before the signature line that reads, "I have read and understood the above information and consent to this procedure." One problem with this part of the consent form is that there is no way to appropriately determine if the volunteer, parent, or legal guardian actually comprehends the material, as compared to just signing the form hoping to improve the quality of life of themselves or their loved one. With an education process proctored by a researcher or lead surgeon, one can appropriately make the conclusion that the parties involved know what is necessary to sign a consent form. To evaluate that conclusion would be a series of quizzes where the pass rate would be determined and recorded by the proctor in order to determine readiness to sign the consent form.

The education plan will be a four day course spanning two weeks, with one to two hours per session. One important point is that since a lot of the information in the education plan is unknown or not yet developed, the plan is only a skeleton online for reference purposes.

- Day 1: Engineering

o Concepts of Device, components of the device and basic science behind it

- Day 2: Risks/Benefits

o Ideal Benefits vs. Worst possible result of procedure (no change after prosthetic)

o Medical/Procedural Risks, both specific to the visual prosthetic and general medical warnings

o This day would be a quiz day, covering Day 1 and 2 (a.k.a. Week 1)

- Day 3: Rehabilitation

o Description of Rehabilitation Program

- Day 4: Extended Care and Terms of Care

o Describes all services offered and extent of services, including time length of care for volunteer related to project, along with services offered at any time. Point will also be made that this is a volunteer process, and volunteers can leave trial at any time.

o This day would be a quiz day, covering information from Day 3 and 4 (a.k.a. Week 2; proctor could also make this a cumulative quiz covering all 4 sessions)