I P R O 3 0 6

ILLINOIS INSTITUTE OF TECHNOLOGY

Planning for Human Implantation of a Cortical Visual Prothesis

PROJECT PLAN

FALL 2008

ADVISOR : PHILIP TROYK

1.0 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.

2.0 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.

F. No additional documents will be attached with the project plan.

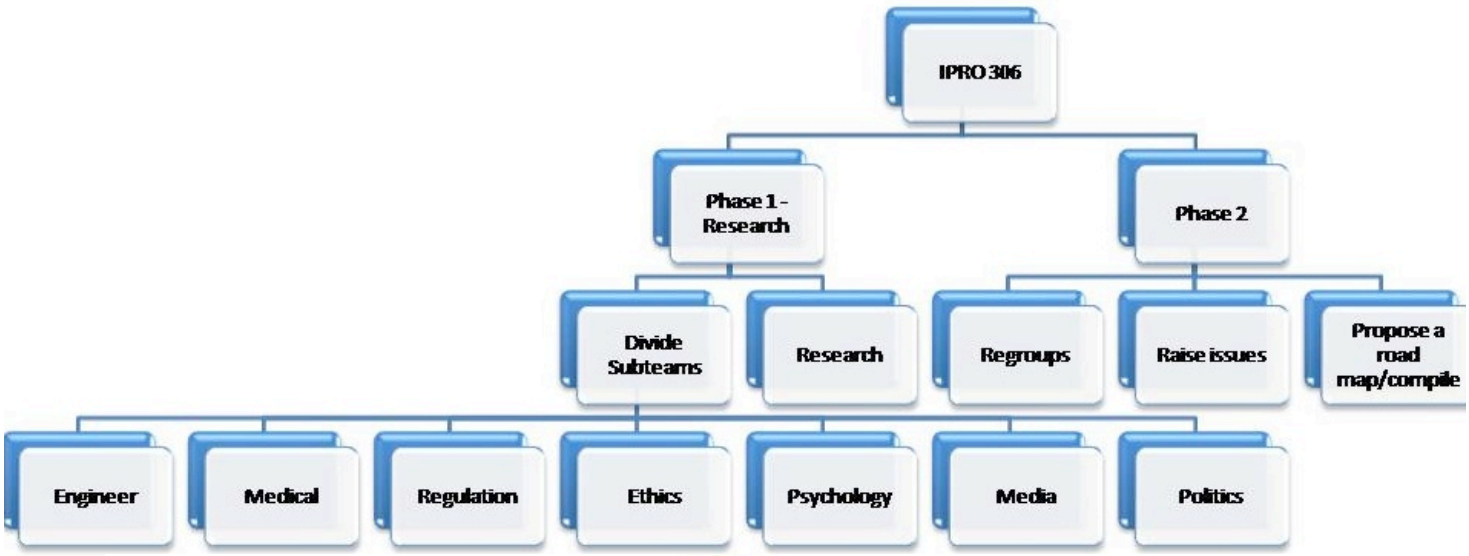
3.0 OBJECTIVES

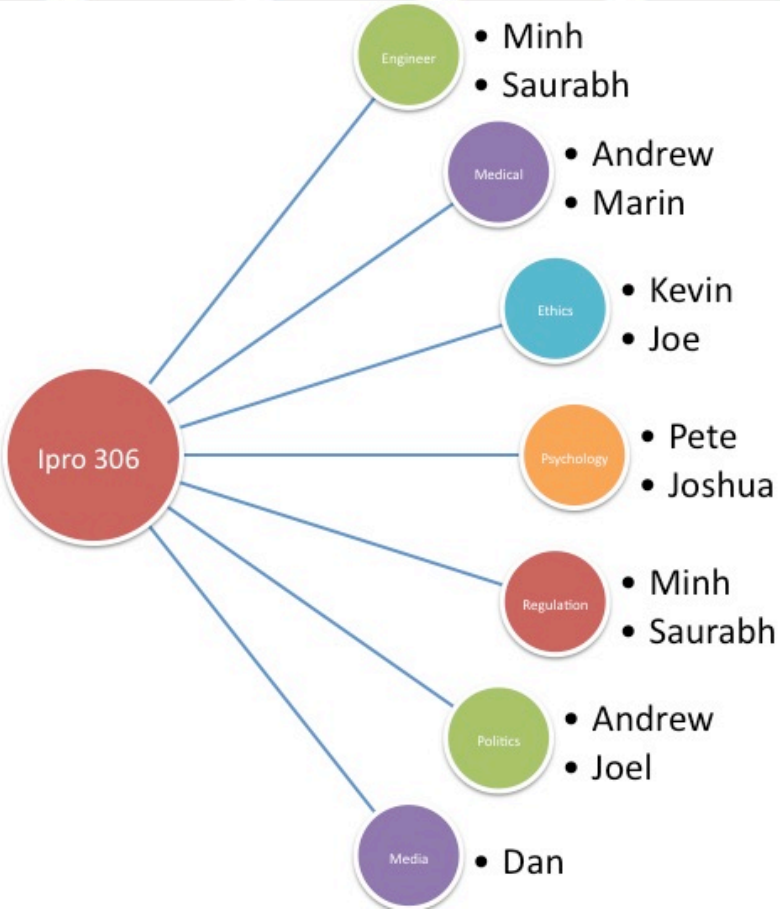
- Review available literature on visual prosthetics, focusing on intracortical, and make an assessment on the status of this technology.
- Expand on the ethical, psychological, medical, regulatory, political, media, and engineering aspects of this new technology.
- Make inferences regarding the overall 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.

4.0 METHODOLOGY

A. Work Structure Breakdowns





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:

- 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 research phase. All members are expected to raise the knowledge levels on the topic during this phase. We divide into seven sub teams and assigned tasks to individuals. iGroups has been organized so team members can upload files to relevant folders. often interact with each other so everyone will be at the same level of understanding. We will also participate in real life interaction (visiting laboratories and the Chicago Lighthouse, interviewing people involved in the project).

We will have a midterm regroups and move forward to Phase 2. At this phase , 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.

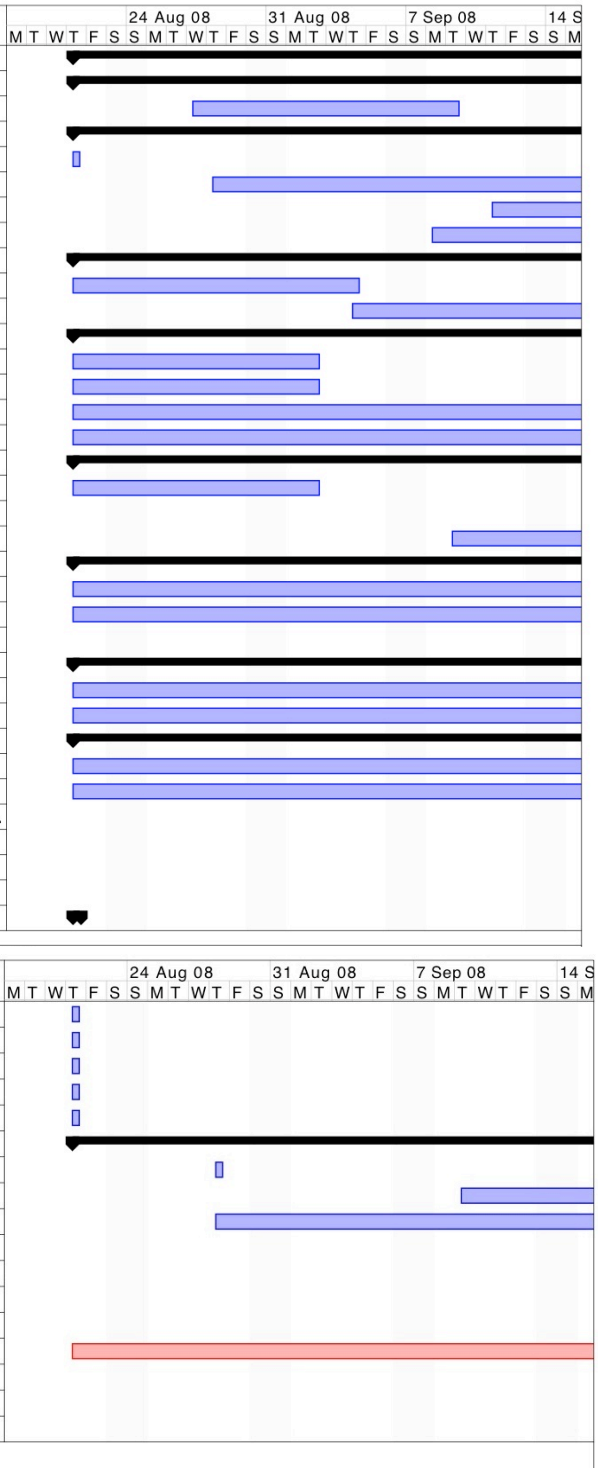
D. Possible Outcomes:

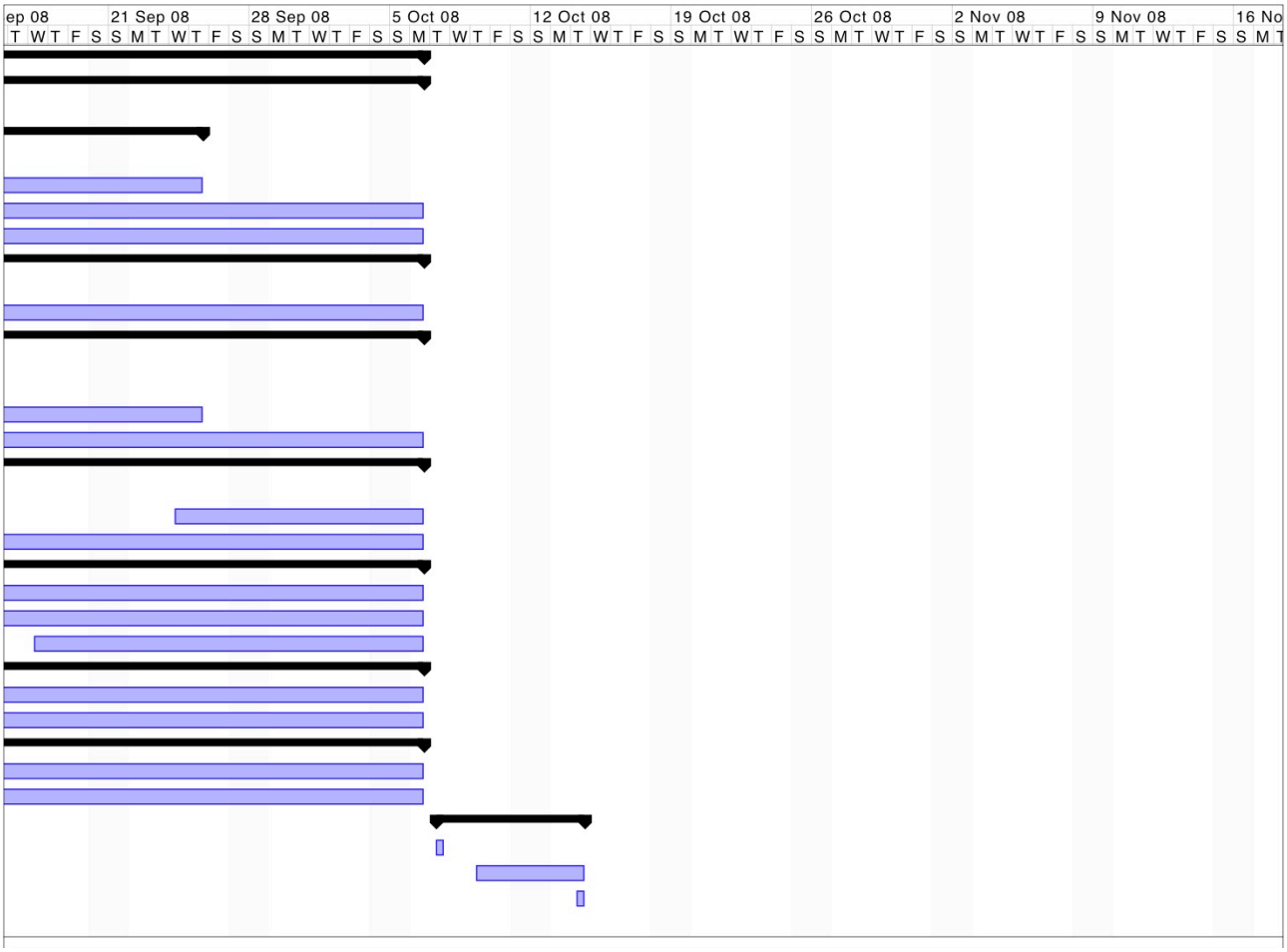
By the end of the project, all members are expected to gain knowledge on the topic. Due to the open ended nature of the topic at hand and because of the different

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.

E. GANTT CHART

	Name	Resource Names
1	**RESEARCH STAGE**	
2	**Engineering Team**	**Saurabh;Minh Tran**
3	Previous Technology	
4	**Current Technology**	
5	Visit IIT Neuro lab	
6	Get all the datas	
7	Devices materials	
8	Human trial ready?	
9	**Regulation Team**	Minh Tran;Saurabh
10	Previous documents to FDA	
11	New device regulations	
12	**Medical Team**	**Andrew;Marin**
13	Pre clinical data	
14	Study previous Animal testing	
15	Background	
16	Identify risks	
17	**Psychological Team**	**Joshua;Pete**
18	Identify psych effects	
19	Study volunteers' reactions	
20	Other concerns	
21	**Ethical Team**	**Joel;Kevin**
22	Selection criterions	
23	Inform of consents	
24	Other ethics problems	
25	**Media Team**	**Dan**
26	Publicity	
27	Education on new technology	
28	**Politics Team**	**Joel;Kevin**
29	Public opinions shifted?	
30	Public policy aspects	
31	**Midterm Regroups**	**Prof Huyck;Prof Troyk;...**
32	Project feedback	
33	Decide on what next?	
34	Divide new groups	
35	**LAST HALF OF THE PROJECT**	**TEAM**
36	Gathering all research information	
37	Raise issues occuring during research	
38	Proposing ideas/issues solution	
39	What is left?	
40	Compile	
41	**IPRO Deliverables**	
42	Team building	
43	Project plan	
44	Team charter	
45	Midterm review	
46	Abstract/Brochure	
47	Poster	
48	Website	
49	Meeting minutes	
50	Final report	
51	Ipro day presentation	
52	IPRO deliverable CD	

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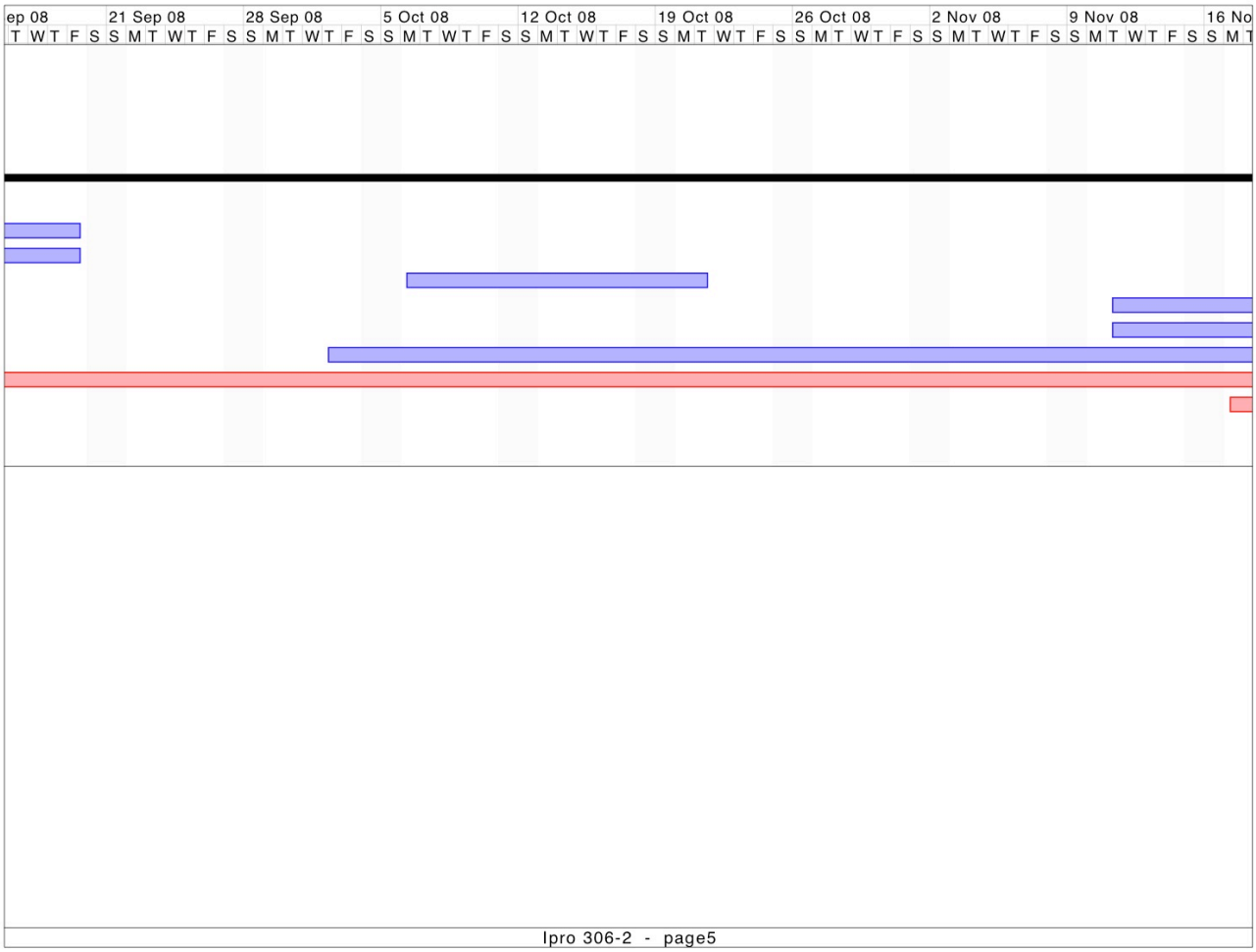
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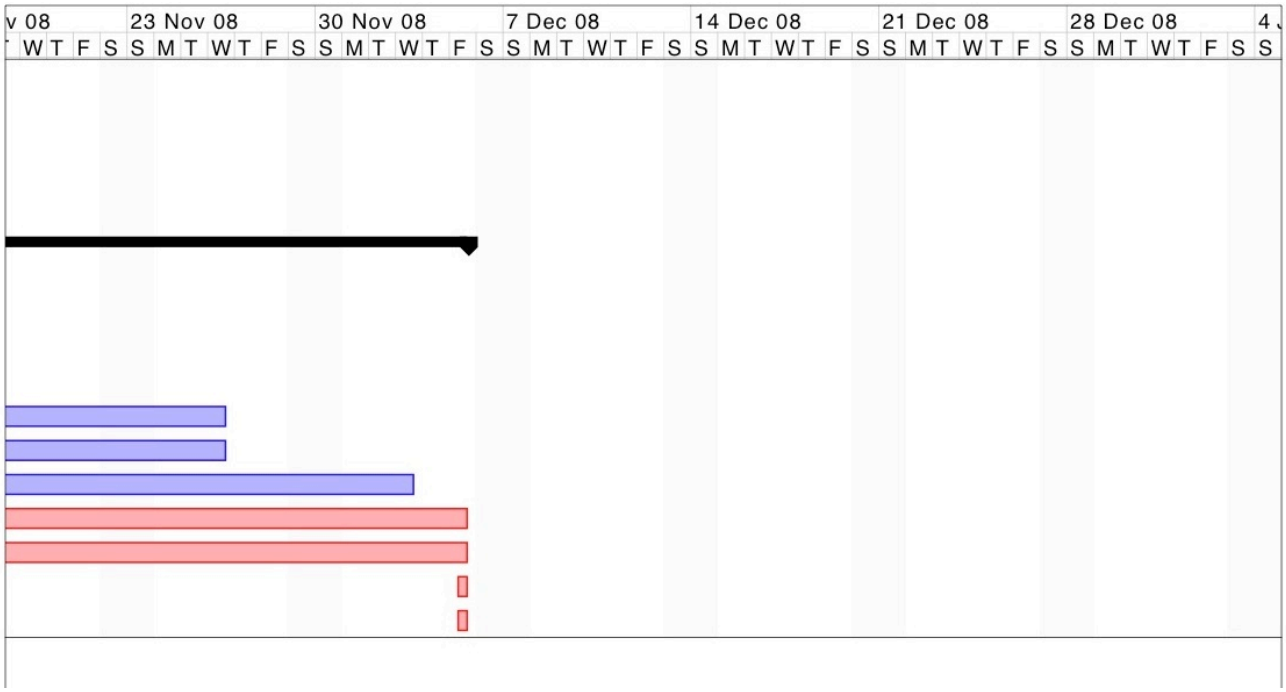
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5.0 BUDGET

ITEMS	COST	EXPLANATION
Out of Class meeting	$250	To thank guests for visits since the members Cortical Visual Prosthetics is located all over the united states and Team building dinner and snacks for out of class dinner.
Airline Tickets for 2 to Baltimore	$1,200	To look at labs to see if they meet FDA standards and to see ask question about the engineering of this devices
Office supplies	$50	Binders and dividers to store paper work
Total	$1,500	

6.0 TEAM STRUCTURE AND ASSIGNMENTS

A.

TEAM MEMBER	MAJOR / YEAR	SKILLS/STRENGTH	EXPERIENCES/ ACADEMIC INTERESTS	TEAM(S)
Andrew Rust	Biology/Senior	Computing. carpentry. research	Botany, Marine biology	Medical & Politics
Dan Tian	Biomedical Engineering/ Senior	Basic computer skills	Lab research (wet lab)/ Research in biomedical Engineering	Media
Joel Kam Sadja	Electrical Engineering	Java, Solid Edge, AutoCad, Ms Office	Super conductors, Shock resistant ceramics	Ethics & Politics
Josh Blackketter	Materials Engineering/ Senior	Editing/Proofreading, Research, Materials Micrography	Material Interfaces	Psychology
Kevin Ragauskis	Biomedical Enigeeering/ Junior	Computer hardware, basic hardware diagnostics, Expansive knowledge of Library database systems	33rd Street Productions, Ipro 310 - Assisted devices for Blind and Visual Impaired swimmers, Viola music, Runs simply strings quartet out of Orland Park	Ethics/Team leader
Marin Assaliyski	Aerospace and Mechanical Engineering / Junior	Great team skills. Reliable and on time	Operating X Ray equipment, Security checkpoint coordinator, Long way backscatter. O'Hare security Inspector	Medical
Minh Tran	Chemical Engineering/ Senior	Engineering skills , team work, Research	2 years working experiences + 2 IPRO experiences. Interest : Renewable Energy , Environmental Regulation	Engineer & Regulation
Peter Mathes	Psychology/ Senior	Focused, experience in different disciplines, cultured.	Focused, experience in different disciplines, cultured.	Psychology

TEAM MEMBER	MAJOR / YEAR	SKILLS/STRENGTH	EXPERIENCES/ ACADEMIC INTERESTS	TEAM(S)
Saurabh Jain	Electrical and Computer Engineering/ Senior	Micro assembly, Microprocessor, solder, debugging circuits. Electronics, Machining, electronics, wire bonding, AutoCad, Assembly language, Java & C +	Researched for the Advanced commutation Laboratory at IIT, Engineering Tech at Sigenics	Regulation & Engineer

Figure 1 - Team roster

B.

Our team has decided to have seven sub-teams to help cover all the different topics dealing with implantation of a device into the human body. Our sub teams are medical, politics, ethics, engineering, media, regulatory and psychology team. We do not have sub team leaders because we only have one or two members in each team.

SUB TEAM	MEMBERS	TASKS
Engineering	Minh Tran & Saurabh Jain	Look at Previous Technology, Understand the intracortical Prosthetics, Figure out the Fundamental requirements, Visit IIT Neuro Lab, Collect data from previous experiments, Identify pros and cons of Devices and determine if the devices is read for human trials, identify all the material used on the chip.
Ethics	Kevin Ragauskis	Identify all ethical problems, safety issues, determine the right type of test subject, Risks vs Benefits, determine inform of consents.
Media	Dan Tian	Marketing, educating the public on the facts of the new technology
Medical	Marin Assaliyski & Andrew Rust	Identify risk associated the devices, and get background data. Need to look at pre- clinical datas and study previous Animal testing to determine if this device is ready for trials on Human volunteers

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Medical	Marin Assaliyski & Andrew Rust	Identify risk associated the devices, and get background data. Need to look at pre- clinical datas and study previous Animal testing to determine if this device is ready for trials on Human volunteers
Psychology	Peter Mathes & Josh Blackketter	Identify Psychological effects , kinds of vision blind people want to restore
Politics	Joel Kam Sadja & Andrew Rust	Assessment on how outsiders feel about this type of technology and determine how to handle public ‘s reactions about the new technology
Regulatory	Minh Tran & Saurabh Jain	Review previous submitted documents to the FDA for other implantation devices, identify steps needed to have a new regulation.

Figure 2- Team structure

C.

TASK	TEAM MEMBER
Minute taker	Dan Tian
Agenda Maker	Kevin Ragauskis
Time Keeper	Kevin Ragauskis
Weekly timesheet collector / Summarizer	Marin Assaliyski
Master schedule maker	Saurabh Jain
iGroups	Dan Tian

Figure 3 - Team project monitoring roles

D.

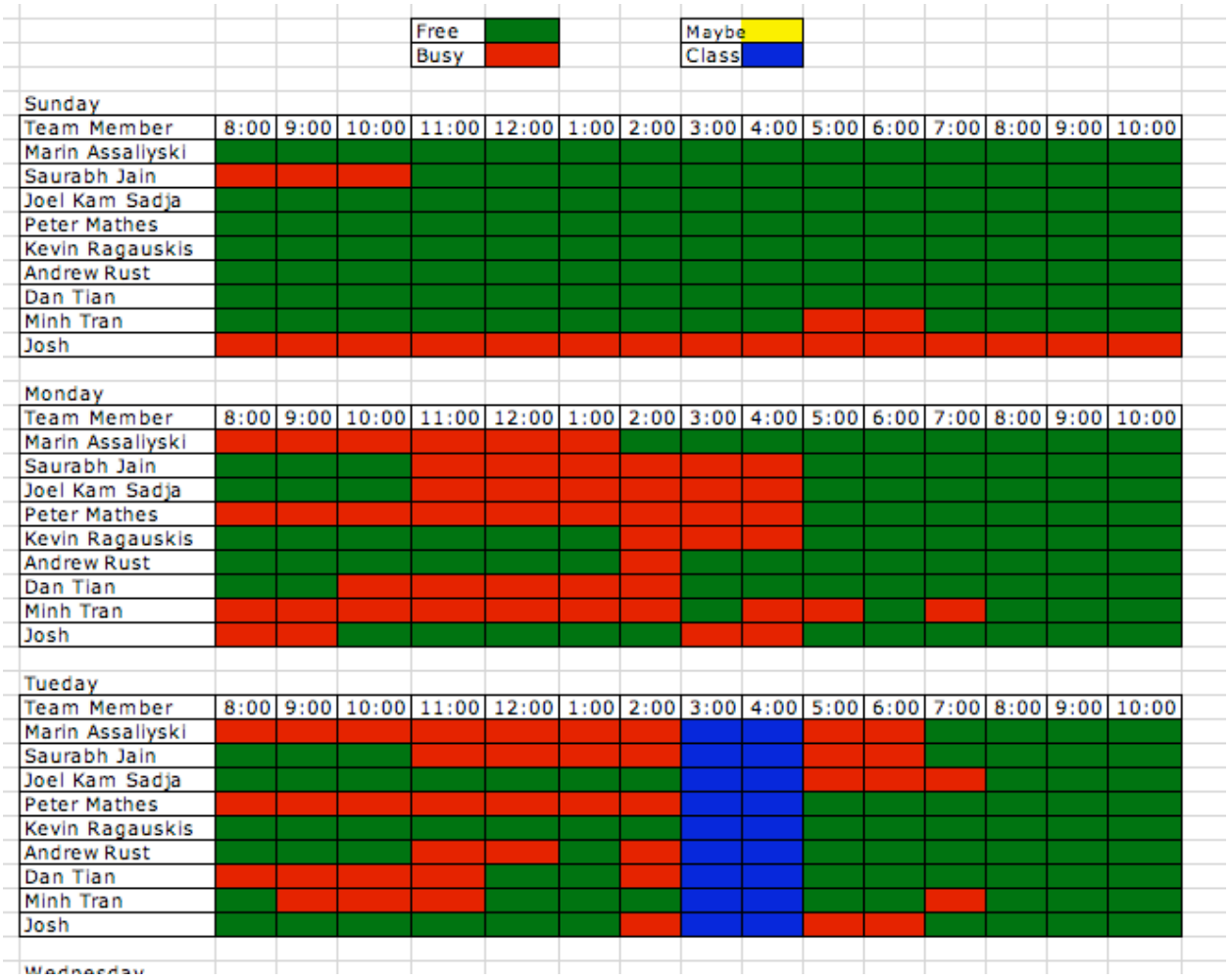
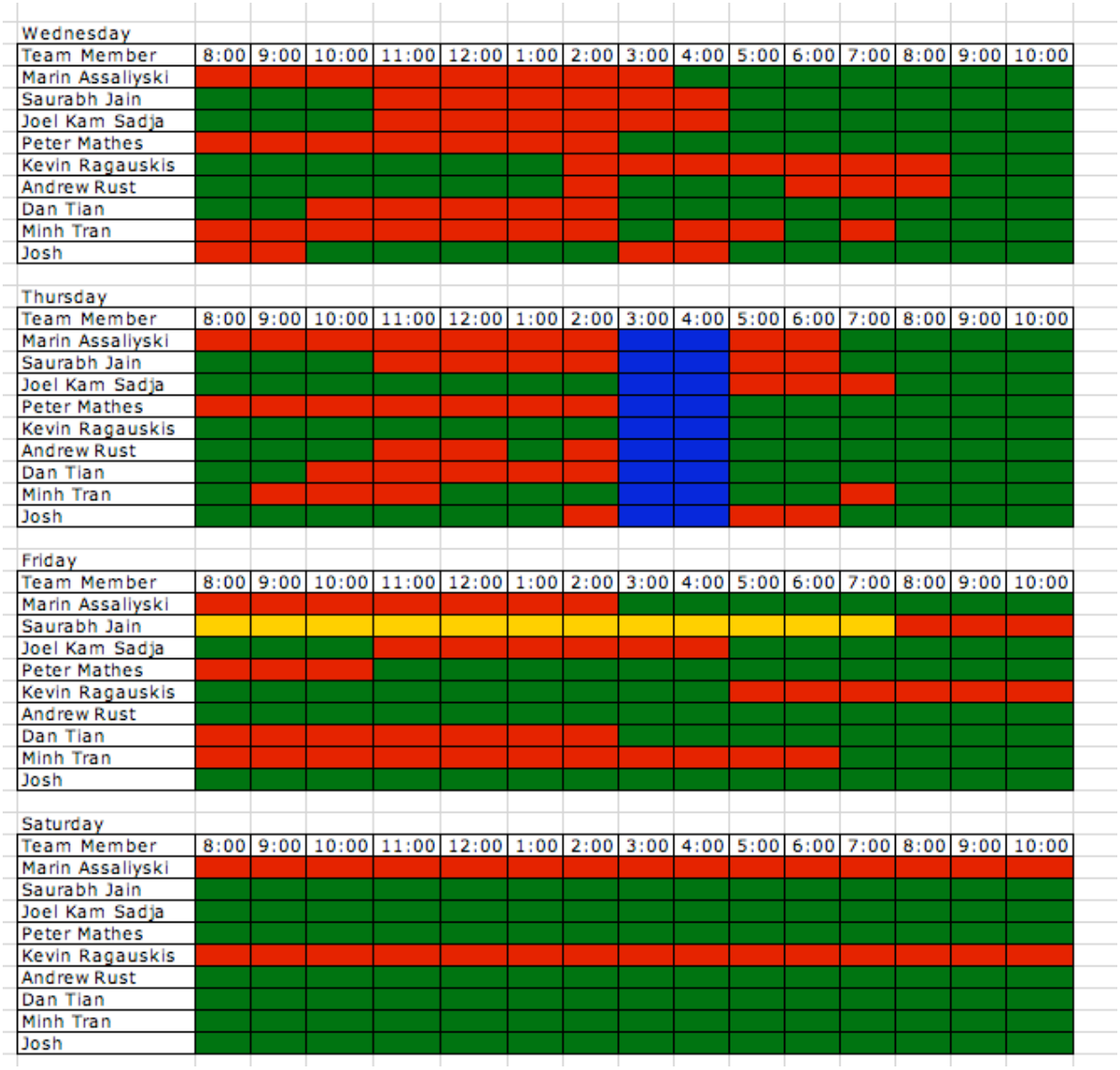


Figure 4- Master schedule - part 1 of 2



Wednesday															
Team Member	8:00	9:00	10:00	11:00	12:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00
Marin Assaliyski															
Saurabh Jain															
Joel Kam Sadja															
Peter Mathes															
Kevin Ragauskis															
Andrew Rust															
Dan Tian															
Minh Tran															
Josh															

Thursday															
Team Member	8:00	9:00	10:00	11:00	12:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00
Marin Assaliyski															
Saurabh Jain															
Joel Kam Sadja															
Peter Mathes															
Kevin Ragauskis															
Andrew Rust															
Dan Tian															
Minh Tran															
Josh															

Friday															
Team Member	8:00	9:00	10:00	11:00	12:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00
Marin Assaliyski															
Saurabh Jain															
Joel Kam Sadja															
Peter Mathes															
Kevin Ragauskis															
Andrew Rust															
Dan Tian															
Minh Tran															
Josh															

Saturday															
Team Member	8:00	9:00	10:00	11:00	12:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00
Marin Assaliyski															
Saurabh Jain															
Joel Kam Sadja															
Peter Mathes															
Kevin Ragauskis															
Andrew Rust															
Dan Tian															
Minh Tran															
Josh															

Figure 5- Master schedule - part 2 of 2