**UNIVERSITY OF COLORADO BOULDER  
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:** eyeCU

**Principal Investigator:** Arielle Blum

**Key Personnel:**

| **Name** | **Role** | **Department** | **Phone Number** | **E-mail** |
| --- | --- | --- | --- | --- |
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**Your participation in this research study is voluntary.** Please think about the information below carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

**Purpose and Background**

Many individuals with paralysis have difficulty with daily tasks, especially individuals with full body paralysis. For those who still maintain the ability to use their eyes unhindered, there is the possibility of using eye tracking as a means of interaction with the world. Eye tracking is the process of tracing the movement of the eyes in order to control a computer cursor.

Currently, there are two types of eye tracking techniques commonly practiced: Bright Pupil and Dark Pupil. Bright pupil tracking employs the use of infrared (IR) illumination of the eye to create greater contrast between the pupil and the iris. In this configuration, the eye tracking robustness and accuracy is significantly improved; however, this technique is not effective in outdoor lighting due to interference from Ultraviolet light. The Dark Pupil technique does not require IR lighting; however, the algorithms for tracking pupils in this configuration are much more complex.

ANSI Z136.1 in the USA and IEC 6085.1 internationally, define classes of lasers depending on their output power and wavelength concerning the prevention of risk and injury. The maximum permissible exposure, MPE, is the highest energy density in , this measure is used to determine whether the light source has a negligible probability for creating damage to the physical structures of the eye. According to the International Commission on Non-Ionizing Radiation Protection, ICNIRP, the recommended daily maximum exposure is total irradiance for wavelengths 770-3000 nm for day-long continuous exposuresFor infrared LEDs, the potential hazards are thermal injury to the retina of the eye and thermal hazards to the lens of the eye.Due to the radiance limitation of LEDs, they cannot produce exposure level at the retina that even approach the levels that are known to cause retinal thermal injury

In terms of advancement of the overall knowledge in the field of eye tracking, this project will provide a significant learning opportunity for students.

**Study Tasks and Procedures**

Participants will wear the eye tracking system and participate in a 30 second calibration process, this enables the eye tracking system to gain information about physiological properties of the participant’s eye. During this process, the eye will be illuminated by an 830nm IR LED and his/her eye will be recorded by a video camera. The length of each of these sessions will last no more than 10 minutes in duration. Furthermore, successive testing must be separated by one hour for each participant. The data collected from each test will be recorded on Secure Digital memory (SD) which will then be archived on a password protected virtual private network (VPN). Additionally, each visit will be on an ‘as needed’ basis. Besides the recording of participant’s eye movements when wearing the eye tracking system, no additional video or audio recording will be conducted.

The datasheet for the video camera can be found attached to this document. The IR LED is VSMG2700, the datasheet for this component can also be found attached to this document.

**Duration**

The project will continue until May 3rd, 2012.

**Study Withdrawal**

If at any time, any of the participants fail to abide by the terms defined for safe testing, then they will be withdrawn from testing. If the participant is withdrawn due to failure to abide by the terms defined for safe testing, then the data previously collected by the former participant will be destroyed. If participants are withdrawn, they will not be replaced.

**Risks and Discomforts**

Due to our adherence to the guidelines presented by the International Commission on Non-Ionizing Radiation Protection there should not be any risks to participants

**Benefits**

There are no overstated benefits to participants; however, participation may help us in the development of the project.

**Confidentiality**

These are some reasons that we may need to share the information you give us with others:

* If it is required by law.
* If we think you or someone else could be harmed.
* Sponsors, government agencies or research staff sometimes look at forms like this and other study records. They do this to make sure the research is done safely and legally. Organizations that may look at study records include:

1. Office for Human Research Protections or other federal, state, or international regulatory agencies
2. The University of Colorado Boulder Institutional Review Board
3. The sponsor or agency supporting the study:

**Participant Rights**

Taking part in this study is your choice. You may choose either to take part or not take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits. We will tell you if we learn any new information that could change your mind about being in this research study. For example, we will tell you about information that could affect your health or well-being.

**If You are Injured**

**Contacts and Questions**

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| --- |
| For questions, concerns, or complaints about this study, call |
| If you are injured as a result of participating in this study or for questions about a study-related injury, call |
| If you have questions about your rights as a research study participant, you can call the Institutional Review Board (IRB). The IRB is independent from the research team. You can contact the IRB if you have concerns or complaints that you do not want to talk to the study team about. The IRB phone number is (303) 735-3702. |

**Signing the Consent Form**

I have read (or someone has read to me) this form. I am aware that I am being asked to be in a research study. I have had a chance to ask all the questions I have at this time. I have had my questions answered in a way that is clear. I voluntarily agree to be in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Name of Participant (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Obtaining Consent (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_