Consent Form

TITLE:	The perceptual experience of Argus II users
PROTOCOL NO.:	IRB Protocol #20213190
CLINICALTRIALS.GOV ID:	NCT05285618
SPONSOR:	National Institutes of Health (NIH)
INVESTIGATOR:	Michael Beyeler, PhD 3201 BioEngineering Santa Barbara, CA 93106 USA

RESEARCH SUBJECT CONSENT FORM

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SPONSOR:	National Institutes of Health (NIH)
INVESTIGATOR:	Michael Beyeler, PhD 3201 BioEngineering Santa Barbara, CA 93106 USA
STUDY-RELATED PHONE NUMBER(S):	(949)287-1057 (949)287-1057 (24 hours)

RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Key Information:

You are being asked to join a research study about your visual experience with the investigational retinal prosthetic device called the Argus II. The goal of the research is to try to develop better stimulation protocols for retinal implants. If you join you will complete behavioral tasks while having your implanted prosthetic stimulated using FDA-approved protocols. Your participation in this study is voluntary. You will have up to 5 sessions that will last 4 hours each. The most important risks or discomforts that you may expect from taking part in this research include fatigue and possible boredom. There is a small risk that you may get temporary headaches. Sometimes you may experience uncomfortably bright flashes of light. You will be

asked to take a break from the experiment until you feel better. The alternative to taking part in this research is not to take part. There is no cost or benefit to you to join.

Why is this research being done?

The purpose of this research is to further our understanding of the visual experience of Argus II users. Clinical experience with existing devices makes it clear that the provided artificial vision differs substantially from normal sight. In the research proposed here, we will combine human behavioral measurements and computational modeling to try to develop better stimulation protocols for retinal implants.

How long will I be in this research?

We expect that your taking part in this research will last 4 hours per session with generous breaks every 30 or 60 minutes (or upon request) and a lunch break. You may return for up to 5 sessions (each carried out on different testing days), for a total of 20 hours.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, we will be stimulating your implanted prosthetic device using FDA-approved stimulation protocols. These stimuli cannot hurt you – you may have experienced similar stimulation upon first device activation or when the clinician is adjusting your thresholds.

You will be asked to sit in a comfortable chair. An experimenter will be present at all times. You may also want to have a sighted person of trust present.

In response to the stimulation or the image on the monitor, you will be asked to make behavioral judgments. Examples include detecting a stimulus "did you see a light on this trial", reporting size by drawing on a touch screen, reporting shape by selecting a tactile object of similar shape, telling us which of two stimuli are brighter, or identifying what letter was presented. Sometimes, we will ask you to verbally report what you saw. Other times we will ask you to use the keyboard or keypad attached to a computer. We will record your answers, the time it took you to respond, and your drawings on the touchscreen, but not any identifiable or confidential information.

Sometimes the experiment will be carried out with the device turned off, or with the relationship between the electrodes and the visual world scrambled.

We anticipate that 15 Argus II users across 3 testing sites will participate in this research study.

MEDICAL RECORDINGS PATIENT CONSENT FORM AND
CONSENT SIGNATURES:

As part of this project, recordings will be made of you during your participation in this research study. You are giving consent to make the types of recordings listed below. You are giving your consent as a voluntary contribution in the interest of medical education and knowledge. In any use of the recordings, we will not disclose your name, however your face may be shown and your voice may be heard.

I consent to the making of:
(Please check as many as apply)
☐ **Video recordings**
☐ **Audio recordings (and transcriptions)**
☐ **Photographs**
☐ **Electronic Images**
☐ **Motion Pictures**

I authorize this under the following conditions:

(1) These recordings, motion pictures, electronic images or photographs may be taken only with the consent of the professional responsible for my care.
(2) The research team responsible for this clinical study can analyze these recordings.
(3) The recordings can be shown at meetings of scientists, doctors, medical practitioners and governmental agencies interested in the development of implantable visual prosthetics. Additionally, these recordings may be shown in public presentations to non-scientific groups.
(4) The recordings will be used for educational or scientific purposes; recordings and information relating to my case may be published and republished, exhibited either separately or in connection with each other, published in professional journals, or used for any other purpose in the interest of medical education, knowledge, or research, however, it is understood that in any such publication or use, I shall not be identified by name.
(5) I waive all publicity and privacy rights that I may have in such recordings as well as any claims for payment of royalties in connection with any exhibition, televising, or other showing of these recordings, regardless of whether such exhibition, televising or other showing is under philanthropic, commercial, institutional or private sponsorship, and irrespective of whether a fee of admission or film rental is charged.
(6) I understand that photographs, electronic images, films or tapes may be edited, modified, or retouched for artistic purposes to withhold identity or for other graphic production reasons which may or may not be within the control of the study.

Your signature indicates that you give full consent to the principal clinical investigator of this study and the Johns Hopkins University to make and use the recordings as described above.

_____
Signature of Participant Date/Time

_____
Signature of Person Obtaining Consent Date/Time

_____
Signature of Witness to Consent Procedures Date/Time
(optional unless IRB or Sponsor required)

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include fatigue and possible boredom. You should request to take breaks as often as needed.

There is a small risk that you may get temporary headaches. Sometimes you may experience uncomfortably bright flashes of light. If you experience any of these discomforts, please let the experimenter know immediately so we can lower stimulation levels to ensure your comfort. You will be asked to take a break from the experiment until you feel better. If you prefer, we will discontinue the session.

There is the risk that information about you may become known to people outside this study.

What treatment costs will be paid if I am injured in this study?

We estimate that it is very unlikely that you will be injured by participating in this study. Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include a better understanding of what limits the perceptual experience of having a retinal implant. It is not expected that you will personally benefit from this research.

Our goal is to try to develop better stimulation protocols for retinal implants, which we hope will benefit individuals with retinal implants in the future.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $800. Your compensation will be broken down as follows:

- You will be compensated at a rate of $20/hour, including travel time.
- You will be paid in cash at the end of each testing day.
- Should you decide to withdraw, you will be paid a pro-rated amount per fifteen minutes that you participated in the experiment.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

What other choices do I have besides taking part in this research?

This study is voluntary and not part of your clinical care. The alternative to taking part in this research is not to take part. Let the researcher know if you no longer want to take part. If you do not join, your care at Johns Hopkins will not be affected.

What happens to the information collected for this research?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

Your private information and your medical record will be accessed only by your physician. Some of these data will become part of the study data in de-identified form and shared with collaborators on this project; "de-identified" means that people seeing the information will not be able to tell from which person the data were collected. This will include fundus photographs (pictures of the implant on the back of your eye) and OCT records (pictures of the health of your retina), and other data related to the positioning and effectiveness of your implant.

Your personal information may be released if required by law. Authorized representatives from the following organizations may review your research data for purposes such as monitoring or managing the conduct of the study: The research team and people who work with the research team, authorized UCSB personnel, WCG IRB (the Institutional Review Board that reviewed this study) and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We may use or share your research information for future research studies. If we use and/or share your information in future research studies or with other researchers it will be de-identified. This research may be similar to this study or completely different. We will not ask for your additional informed consent for future use of your de-identified data.

Tests done for this study are not meant to provide clinical information and we have not intention to make any medical diagnosis. We will not provide you with any individual research results.

What happens if I want to stop taking part in this study?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end

your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Who can answer my questions about the study?

If you have any comments, concerns, complaints, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems, questions, complaints or concerns you may have about the study, please contact the Johns Hopkins Medicine IRB at 410-502-2092 or jhmeirb@jhmi.edu.

This study has been reviewed by WCG IRB, a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may also contact the JHMI IRB at 410-502-2092 or jhmeirb@jhmi.edu.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.

- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

Statement of Consent

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time