If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Studies of visual perception with the Argus II implant.**

Application No.: **IRB00045074**

Sponsor: **National Eye Institute**

Principal Investigator: **Gislin Dagnelie, Ph.D.**
Johns Hopkins Hospital
600 N. Wolfe Street, Wilmer Woods 358
Baltimore, MD 21287
Phone: 443-287-0072 Fax: 410-955-1829

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

2. Why is this research being done?

This research is being done to gain better understanding of the Argus II device and its potential benefits.

We are interested in learning how Argus II wearers use their implant, and how we can further improve the benefits to the user either by adjusting functions performed by the Video Processing Unit (VPU), or by modifying the image the VPU receives from the camera.

People who are enrolled in the Argus II Post-Approval Study (NA_00087968) or other interested post FDA-approval Argus II retinal implantees or Argus II Retinal Implant System feasibility study (NA_00008133) may join this study.

How many people will be in this study?
About 20 people will take part in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

You will be asked to perform some additional practice tasks and vision tests during your study visit for the Post-Approval Study (NA_00087968) or the Argus II Retinal Implant System feasibility study (NA_00008133).

- This may include practicing specific tasks using your Argus II retinal prosthesis system, and performing a number of other tests to better understand how you use the device and how future Argus II implantees may have more benefit from its use.
- These practice tasks and tests may be done in the laboratory or your home, or be carried out in your community.
- Typical examples include grabbing and manipulating objects, interacting with standing or moving people and obstacles, finding your way in familiar and unfamiliar settings, and self-care. The images you will see may be filtered or enhanced to see if this will help you better understand the tasks.
- As much as possible, the study visits for this new study will be held at the same time as study visits for the other study you are currently enrolled in; the Argus II Post-Approval Study (NA-00087968) or Argus II Retinal Implant System feasibility study (NA_00008133); as outlined in the consent forms for those studies.
- We may ask you to come in for additional study visits especially if you are enrolled in the Argus II Retinal Implant System feasibility study (NA_00008133).

How long will you be in the study?
You will be in this study for up to 3years.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

4. What are the risks or discomforts of the study?

Similar to the Post-Approval Study (NA_00087968) and Argus II retinal Implant Feasibility Study (NA_00008133), in which you are currently enrolled, or periodic post implantation device checks, study team members will oversee all practice and testing. Moreover, these activities will be no different from those normally undertaken by blind and partially sighted individuals. Therefore, the study will not add appreciable risk to that of being blind and having a retinal prosthesis system.
You may find that the additional time to take part in these study procedures may be an inconvenience to you; however, we will try to schedule the study visits at the same time as study visits for the other study in which you are currently participating.

There is a risk that information about you could become known to people outside of this study.

5. Are there risks related to pregnancy?

As in the Argus II Post-Approval Study (NA-00087968) and Argus II Retinal Implant System feasibility study (NA_00008133), if you are pregnant or wish to become pregnant during the duration of the study, you cannot be enrolled.

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

There are no alternatives to this study to obtain this type of information from people with your eye condition. You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

The tests that will performed in this study will be at no cost to you or your insurance. Study expenses for the study will be paid for by the sponsor.

9. Will you be paid if you join this study?

You will not be paid for your participation in this study. However, we will be providing lunch vouchers and travel reimbursements to compensate for the additional time spent during your study visit.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Your doctor determines that it is in your best interest
- The study is cancelled
- You fail to follow instructions.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory will know your identity and that you are in the research study. Other people at Johns Hopkins, for example your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. 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.

13. What treatment costs will be paid if you are injured 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.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Gislin Dagnelie at 443-287-0072. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Judith Goldstein at 410-955-0580 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Wilmer Retina Service at 410-955-3518.

d. What happens to Data that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

15. What does your signature on this consent form mean?

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

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

(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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(s) of this study and Second Sight Medical Products, Inc. to make and use the recordings as described above.

_____

Signature of Participant Date/Time

_____

Signature of Person Obtaining Consent Date/Time

_____

Signature of Interpreter/Witness to Consent Procedures Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)