UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Fluorescence Imaging of Healthy Human Eyes

Company or agency sponsoring the study: This study is not sponsored by any external organization

Principal Investigator: Joshua M. Herzog, Ph.D., Department of Mechanical Engineering, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand how to diagnose eye infections using cameras and ultraviolet lights, or “blacklights”. In order to do this, a series of pictures will be taken of one or both of your eyes while under a low-power ultraviolet light.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include new symptoms from use of the imaging device such as mild eye irritation. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by making it easier for doctors to identify and diagnose eye infections. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be less than one hour.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We aim to develop a new medical device that will allow physicians to diagnose eye infections in a quicker, easier, and more accurate way. To do this, a patient's eye needs to be illuminated with ultraviolet light. Infections then glow in a characteristic way. Ultraviolet light can also cause a faint glow in the other parts of a person's eyes, like "glow-in-the-dark" objects. Interference between the two sources of "glowing light" makes it difficult to diagnose with our new device. By illuminating people's healthy eyes with ultraviolet light and taking pictures of the "glow", we can figure out how to improve our device and make it easier for doctors to help people with severe eye infections.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adults ages 18+ that are in good health, and have never had cataract surgery can take part in this study.

3.2 How many people are expected to take part in this study?

30 participants are expected to contribute to this study

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

1. *Screening and information collection:*
    a. You will be asked to provide/sign the following standard information:
        i. Consent to participate in the study
        ii. A statement that you are in good health
        iii. Demographics including gender, race/ethnicity, and age
        iv. Eye color
        v. Contact lens usage (type, frequency, duration of use, and last use)
        vi. History of any eye illnesses, injuries, or other conditions
        vii. If you require eye glasses only:
            1. Diagnosis (e.g., astigmatism, near-sighted, far-sighted, etc.)
            2. Eyeglass prescription if known

2. *Imaging procedure:*
    a. You will be asked to:
        i. Remove your eyeglasses or contact lenses (if applicable).
        ii. Remain seated for approximately 15 minutes.
        iii. Close one eye, and focus your other eye directly ahead for periods of 15 seconds at a time.
    b. During this time, a researcher will:
        i. Place a scientific camera system near your eye.
        ii. Illuminate your eye with a low-power blue light.
        iii. Take a series of pictures of your eye using the camera system.

iv. Illuminate your eye with an ultraviolet light (you may see a blue flash).
v. Take a second set of pictures of your eye using the camera system.

c. This procedure will be repeated for your other eye given your consent.
d. Lastly, you will be asked to answer a couple brief questions regarding:
   i. Any discomfort you may have experienced during the procedure
   ii. Any difficulty you may have had following the provided instructions
e. This procedure is expected to be done on the same day as (1)
f. You will be given the opportunity to view the images

3. *Follow-up phone call (optional)*
   a. A researcher will follow up with you via phone 24 hours after (2) to see if you have any discomfort or other symptoms from the experiment.

All parts of this study will be performed on the University of Michigan campus.

4.2 How much of my time will be needed to take part in this study?
Screening is expected to take less than 10 minutes. The experimental imaging procedure is expected to take 15 minutes or less, and the follow-up phone call is expected to take less than 5 minutes. Approximately 30 minutes of your time is needed in total.

4.3 When will my participation in the study be over?
Your participation in the study will be over after the last follow up phone call is completed.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are exposure to ultraviolet light, which can cause photokeratitis ("snow-blindness"; temporary damage to the front cells of the cornea, or front window of the eye), conjunctivitis ("pink-eye"), and in severe cases cataracts. Long-term exposure to ultraviolet light can also increase your risk for developing certain types of non-cancerous eye growths including pterygium and ocular surface squamous neoplasia. (It is not currently known whether long-term ultraviolet exposure increases your risk for eye cancers.) Possible symptoms of photokeratitis include eye pain, light sensitivity, decreased vision, tearing up, redness in or near the eye, or a gritty sensation in the eye.

The researchers will try to minimize these risks by limiting the amount of ultraviolet light used to less than 1% of what is typically needed to cause any adverse effect. The amount of ultraviolet exposure you will receive during this study is significantly less than most people typically receive in a day.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

If you experience any discomfort during the imaging procedure, it will stopped immediately.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

Participating in other studies that use ultraviolet radiation, or participating in studies that require you to take medications that can affect your eye health could increase your risk of having an adverse reaction to the imaging procedure.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
This study is entirely voluntary. You are not required to participate in this study in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to

tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
If you decide to leave the study after having completing the imaging procedure, it may not be possible to delete your data if it has already been anonymized and included in an analysis.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
No, you will not be paid for taking part in this study.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study:
The University of Michigan is an owner and both Joshua Herzog and Volker Sick are named inventors on a patent application. This means that the University of Michigan, Joshua Herzog, and Volker Sick could gain financially from the results of this study in the future.

The University of Michigan:
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the

information to you. Additionally, your research data will be anonymized shortly after it is collected, meaning that it will no longer be possible to identify which data came from you.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has

been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Joshua M. Herzog
Mailing Address:	2350 Hayward St., 2454 GG Brown, Ann Arbor, MI 48109
Telephone:	(734) 763-8520

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name:

_____

Signature:

_____

Date of Signature (mm/dd/yy):

_____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name:

_____

Signature:

_____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name:

_____

Signature:

_____

Date of Signature (mm/dd/yy):