Mount Sinai
MEDICAL CENTER

INFORMED CONSENT FORM

Comparative Investigation of a Water Bath Technique for Ocular Ultrasound Imaging vs. Traditional Gel-Based Technique - A Pilot Study

YOU ARE ASKED TO READ THE FOLLOWING FORM TO MAKE SURE THAT YOU COMPLETELY UNDERSTAND WHAT WILL HAPPEN IF YOU AGREE TO TAKE PART IN THIS RESEARCH STUDY. THIS INFORMED CONSENT FORM MAY CONTAIN WORDS THAT YOU DO NOT UNDERSTAND. PLEASE ASK THE STUDY DOCTOR OR THE STUDY STAFF TO EXPLAIN ANY WORDS OR INFORMATION THAT YOU DO NOT CLEARLY UNDERSTAND. SIGNING THIS FORM MEANS THAT THE STUDY HAS BEEN EXPLAINED TO YOU AND THAT YOU GIVE YOUR PERMISSION TO TAKE PART. THE FEDERAL GOVERNMENT REQUIRES YOUR APPROVAL IN WRITING BEFORE YOU TAKE PART IN ANY RESEARCH STUDY. IT IS IMPORTANT THAT YOU KNOW WHAT WILL TAKE PLACE AND WHAT RISKS ARE INVOLVED BEFORE YOU DECIDE WHETHER OR NOT TO TAKE PART IN THIS STUDY.

1. RESEARCH PURPOSE AND DURATION

You are being asked to take part in a research study as a healthy volunteer. This study is a prospective, comparative, crossover design. The purpose of this study is to compare two different ways of performing an eye (ocular) ultrasound. The first method uses a clear adhesive bandage (such as Tegaderm), gel, and gentle pressure from the ultrasound probe directly on the closed eyelid. The second method uses swimming goggles filled with water (with the lens removed), allowing the ultrasound probe to hover above the eye without directly touching the eyelid. We are doing this study to see if there are any differences in the quality of the ultrasound images, the presence of any imaging problems (called artifacts), and how comfortable each method is for patients. There will be approximately 16-18 research participants in this study. The expected duration of participation consists of roughly around 10 minutes of active ultrasound scanning (around 5 minutes per method), and around 1-2 minutes for a short post-study survey.

2. PROCEDURES

If you agree to take part in this study, you will act as both the case and control. This means that we are testing both the standard technique of how ocular ultrasonography is currently performed, as well as testing the novel device in order to make comparative measurements. If you take part in this study you will have both of the following procedures done:

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- For the standard eye ultrasound, a clear bandage (ie. Tegaderm) will be placed over your closed eye. The bandage keeps the ultrasound gel from getting into your eye. After the bandage is in place, ultrasound gel will be applied on top, and the ultrasound probe will gently press on your eyelid to take pictures. Several images of your eye will be saved, but no personal information will be recorded—only your assigned study number.

- The novel eye ultrasound technique will consist only of swimming goggles with the lenses removed and filled with sterile water. The ultrasound probe will be hovered above the closed eye, without direct contact. Again, several images will be recorded and saved, without recording any personal information other than your assigned number.

3. RISKS OR DISCOMFORTS

While you are taking part in this study you may be at risk for certain side effects or discomforts. There may also be other side effects or discomforts we cannot predict. Risks and side effects related to the standard ocular imaging include: it is likely to have irritation from the adhesive, unintentional stripping of hairs from the eyelashes and/or eyebrows, and/or discomfort from the probe pressure. It is less likely to have skin irritation from the ultrasound gel and/or eye irritation from the ultrasound gel. It is less likely but serious to have an infection from the gel if it gets into your eye. Risks and side effects related to the novel device include: it is likely to have discomfort from the device, skin irritation from the device, eye irritation from the tap water, and/or water damage to clothing. Most of these effects go away shortly after the imaging techniques are stopped, and are not expected to be serious or long-lasting or permanent.

4. BENEFIT(S) TO YOU

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with ocular complaints in the future.

5. ALTERNATIVE PROCEDURES OR FORMS OF TREATMENT

While there are no particular alternatives, this is an optional study with the alternative to decline participation.

6. COST TO YOU FOR TAKING PART IN RESEARCH STUDY

There will be no cost to you for taking part in this research study.

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7. PAYMENT FOR TAKING PART IN RESEARCH STUDY

You will not be paid for taking part in this research study.

8. CONFIDENTIALITY

Your role in this research study and any information collected about you in this study, including your medical records (known as Protected Health Information, or "PHI") will be protected as required by state and federal laws (including HIPAA) that govern the confidentiality and privacy of medical, personal and genetic information. If your PHI is being used in this research study, you will be asked to sign a specific permission form called an "Authorization" which explains who can see this information and how it can be used. Without your authorization, we may also use or disclose information related to your medical, personal or genetic condition if any information that could identify you has first been removed or a waiver (of Authorization) is approved by the IRB. Whether your PHI is being collected, or not, the following parties may look at and/or copy your study related records for research, quality assurance, and data analysis:

(A) Government agencies or agents authorized by the federal government, including the Food and Drug Administration and the Office for Human Research Protections at the Department of Health and Human Services
(B) Other persons set forth in MSMC's Notice of Privacy Practices if permitted or required by law.
(C) Members of the Institutional Review Board

9. COMPENSATION FOR RESEARCH-RELATED INJURY

There are no plans to provide financial compensation for research-related injury or loss of wages; however, necessary emergency medical care will be provided at Mount Sinai Medical Center. You will be responsible for all costs of this care if not covered by your health insurance or Medicare. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

10. WHOM TO CONTACT FOR ANSWERS

If you do not understand anything related to this study or have an injury, illness or problem related to your taking part in this study, please contact Robert Farrow, DO (317) 374-0982, or Andreea Popa, MD at 985-710-1828 or Danielle Glaze, DO at 850-748-0588 at once.

For questions about your rights as a research participant, contact the Director of the Mount Sinai Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (305) 674-2790.

11. PARTICIPATION IS VOLUNTARY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. This will not affect your continued medical care and treatment by your doctor. Your doctor may ask you to leave this study if he/she feels it is appropriate or necessary. Your doctor will notify you if this should occur. This in no way will affect your continued medical care and treatment by your physician. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

12. I HAVE READ THIS INFORMED CONSENT FORM AND HAVE BEEN GIVEN THE OPPORTUNITY TO DISCUSS AND ASK QUESTIONS ABOUT THIS RESEARCH STUDY. I HAVE ALSO RECEIVED A COPY OF THIS INFORMED CONSENT FORM AND AGREE TO TAKE PART.

Printed Name, Address & Telephone No of Participant:

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Signature of Participant **Date**

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Printed Name of Person Obtaining Consent

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Signature of Person Obtaining Consent **Date**

APPROVED

***I attest that the person who explained the study to the subject is qualified and properly delegated for that task.**

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***Signature of Principal Investigator**