Use of Ocular Point of Care Ultrasound in Diagnosing Retinal Detachment in the Emergency Department: A Prospective Study.

NCT# 5170078

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LOMA LINDA UNIVERSITY
School of Medicine
Department of Emergency Medicine

INFORMED CONSENT

TITLE: *Use of Ocular Point of Care Ultrasound In Diagnosing Retinal Detachment in the Emergency Department: A Prospective Study*

PRINCIPAL INVESTIGATOR: *Dr. Stephanie Tseeng, MD*

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this research study because you have come to the Emergency department with new vision problems or loss of vision.

Only people who choose to take part will be included in the research study. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Patients with recent vision changes or loss of vision may be suffering from a condition known as "Retinal Detachment." This is a serious illness that must be diagnosed and treated rapidly, as permanent vision changes or loss may occur if nothing is done.

We are studying different ways in which we can use the ultrasound to better diagnose retinal detachments and similar visual illnesses. You will be asked if it is okay for us to perform an ultrasound of your eye (which may be in addition to an ultrasound you have already been given by the doctor that is treating you in the emergency room). This will only take a few minutes and will not interrupt or delay any necessary treatment.

This research study will be the first part of a series that involve ultrasound to help manage patients with recent visual changes or loss. About 300 eligible patients will be enrolled across 4 sites, including Loma Linda University.

You will be eligible to participate in this study if:
- You have new painless vision changes

Prospective Study
- You are able to give informed consent to the doctor wishing to perform the study
- You do not have a recent diagnosis from an ophthalmologist
- You do not have any major traumatic injury to the eye

Your participation in this study may last up to 1 day.

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

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HOW WILL I BE INVOLVED?
If you choose to volunteer for the study, you will agree to have an ultrasound examination performed of your affected eye or eyes:

You will have a Tegaderm patch (Thin clear plastic sticker) placed over your eye to protect it from the ultrasound probe and gel. This will also help with making the exam more comfortable and to make clean-up easier.

We will then place a small amount of clean ultrasound gel over the patch so that we can use the ultrasound wand. This should cause no discomfort.

We will then begin the ultrasound examination by placing the ultrasound wand onto the gel, which is touching the patch right above your affected eye. We will record some of the ultrasound images and video. We will also move the wand in specific directions. Lastly, we may ask you to move your eye up-and-down or side-to-side. The total time for this ultrasound session will be about five to ten minutes.

When we are finished with the examination, we will clean off the ultrasound gel, remove the patch, and make sure you are comfortable. This will be the end of the examination.

If at any time you feel faint or experience any discomfort, please let the provider know. You may be experiencing symptoms related to the pressure placed on your eye during the exam or due to anxiety related to your symptoms or the study. The study poses no threat to your eyesight but if your discomfort continues or is severe, you may be removed from the study.

WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?
This study poses no greater risk to you than what you routinely encounter in day-to-day life. Participating in this study will involve the following risks:

Placing and removing of the "Tegaderm" skin patch may cause very slight discomfort, and the ultrasound gel may cause minimal discomfort, as it might be a slightly cool to the touch.

The ultrasound session itself may cause some discomfort due to the gel or pressure of the probe. However, the vast majority of people who have ultrasounds do not have any significant or lasting symptoms.

Should you feel any discomfort which is too much for you, or should you feel unwilling to participate at any time, you are free to let the doctor doing the exam know, and we will stop immediately.

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Data identifying you will only be available to the LLU study personnel analyzing the results.

The use of your Protected Health Information is explained in the separate authorization form .

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WILL THERE BE ANY BENEFIT TO ME OR OTHERS?
Although you may not personally benefit from this study, your participation may help practitioners better identify/provide insights in patients that come to the emergency department with symptoms similar to yours. We are performing this study on a small number of patients in order to show that ultrasound of the eye can be performed in a way to achieve better results than before. If we see that there is benefit, we will look into performing a larger study.

WHAT ARE MY RIGHTS AS A SUBJECT?
Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. Your decision whether or not to participate or terminate at any time will not affect your future medical care with the researchers. You do not give up any legal rights by participating in this study.

WHAT COSTS ARE INVOLVED?
There is no cost to you for participating in this study.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?
You will not be paid to participate in this research study.

WHO DO I CALL IF I HAVE QUESTIONS?
Cal) 909-558-4647 or e-mail patientrelations@llu.edu for information and assistance with complaints or concerns about your rights in this study.

SUBJECT'S STATEMENT OF CONSENT
- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

Signature of Subject Printed Name of Subject

Date

INVESTIGATOR'S STATEMENT
I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

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Signature of Investigator | Printed Name of Investigator

Date

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

RESEARCH PROTECTION PROGRAMS
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TITLE OF STUDY:	Use of Ocular Point of Care Ultrasound in Diagnosing Retinal Detachment in the Emergency Department: A Prospective Study.
PRINCIPAL INVESTIGATOR:	Dr. Stephanie Tseeng, MD
Others who will use, collect, or share PHI:	Authorized LLU Study Personnel

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, address, telephone number, date of birth, and medical records and charts, including the results of the eye exams, ultrasound and disposition reports from this specific visit.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University, health care providers who provide services to you in connection with this study, and other entities as required by law.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

Loma Linda University
Adventist Health Science Center
Institutional Review Board
Approved 8/23/17 Void after, 8/20/2018
5170078 Chair

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

- The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at (909) 558-4344.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

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Approved 8/23/17 Void after 8/20/2018
#5170078 Chair Travis Losey