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I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Objective, Prospective Measurement of Anterior Chamber Cell Grading Using Anterior Chamber Ocular Coherence Tomography
Principal Investigator: David S. Chu, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. David S. Chu is the Principal Investigator of this research study (David S. Chu, MD). A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Chu may be reached at

Institute of Ophthalmology and Visual Science
Doctors Office Center
Suite 6100
Newark, NJ 07103
(973) 972-2064

The study doctor (Dr. Chu) or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: Institute of Ophthalmology and Visual Science

Why is this study being done?

This study is being done to help find better treatments for uveitis. Uveitis is a disease where parts of the eye become sick (inflamed). Doctors know when the eye is sick by looking with a microscope. But even with the microscope, it is difficult for inexperienced doctors to tell exactly how sick the eye is. We want to take a picture of the eye. We hope that the picture will be able to tell us how sick the eye is more accurately. Then, we may be able to better care for patients with uveitis.

Why have you been asked to take part in this study?

Two groups of people are asked to take part in this study. You are being asked to take part in this study because you are in one of the groups.

The first group of people have uveitis or just had cataract surgery in the last 30 days. Being in this group means that your eye has inflammation. Your eye may only have a little bit, or a lot of inflammation. We want to take a picture of your eye to see how accurately the picture can tell how much inflammation there is.

The second group of people may or may not have uveitis. Being in this group means that your eye is not sick (not inflamed). We want to take a picture of your eye to make sure that our picture can tell that your eye is not sick. This will help to make sure our pictures are accurate.

Who may take part in this study? And who may not?

People with and without uveitis can take part in this study. If you have uveitis, you can have active or inactive inflammation in at least one eye. Some people can participate if they had cataract surgery in the last 30 days. You must be 18 years or older to take part in this study. You must also speak English to take part in this study. If you have a certain type of eye disease (cornea opacity), then you cannot take part in this study. If you are pregnant, a minor, or cannot provide consent, then you cannot take part in this study.

How long will the study take and how many subjects will participate?

Up to 300 people will participate in this study. For you, the study will last only a few weeks. The study only happens during your regular doctor visits.

What will you be asked to do if you take part in this research study?

If you want to take part in this study, we will take a picture of your eye. The machine that takes the picture is called an OCT machine. We normally use this machine every day to take pictures of different parts of people's eyes. In this study, we will take a picture of the front of your eye to see how much inflammation it has.

When you return for your next two appointments, we will ask to take another picture. These pictures will be the same exact type as the first one.

Up to 3 pictures may be taken for this study.

If you are not a patient or did not have an eye exam on the date of your enrollment, you will also undergo a non-contact eye exam. This entails sitting in the examination chair while the doctor looks in your eye with a light. The exam will occur on the same day as the pictures from the OCT machine. If you are not a patient, you will not be asked to return for a follow up photograph. However, if you return to the clinic for another reason and would like to continue with the study, then you will be asked to have another picture. We would take these pictures on a maximum of 2 follow up visits, for up to 3 pictures total.

What are the risks and/or discomforts you might experience if you take part in this study?

The study will take about 10-20 minutes of your time at each visit. There is also a small chance of a breach of confidentiality if the data is stolen or misplaced. The OCT uses infrared light that is safe for your eyes.

If you become pregnant during the course of this study, you should notify the study doctor of this fact as soon as possible.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be

- A potentially new understanding of uveitis and inflammation that could lead to better treatments in the future.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

Your alternative is not to take part in this study. Your decision to take part or to not take part will not affect your relationship with Dr. Chu (David S. Chu, MD), Dr. Rescigno (Ronald Rescigno, MD), this clinic, or anyone else on the study team or in the clinic. Your decision to take part or to not take part will also not affect your treatment.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There will be no cost to you. This study will take 10-20 minutes of your time after your regular doctor's visit.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

All of the information we gather will be kept in locked and encrypted files. Your name will be kept in a separate locked file from your data. Only the study coordinator and the principle investigator will have access to your personal information.

A description of this clinical trial will be available on 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.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to David S. Chu, MD, Institute of Ophthalmology and Visual Science, Doctors Office Center, Suite 6100, Newark, NJ 07103.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

David S. Chu, MD
Institute of Ophthalmology and Visual Science
Doctors Office Center
Suite 6100
Newark, NJ 07103
(973) 972-2064

If you have any questions about your rights as a research subject, you can call:

Rutgers Health Sciences - Newark, IRB Director.
(973)-972-3608

Human Subject Protection Program
973-972-1149

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Medical history or treatment
- Laboratory/diagnostic tests or imaging
- Operative reports (about a surgery)

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The U.S. National Institutes of Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:

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How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the research study.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____