PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Prospective Evaluation of Retinal Imaging and Clinical Data for Prediction of Ocular and Systemic Disease

STUDY DOCTOR: Sai H Chavala, MD

STUDY SITE: SpectOcular
11615 Forest Central Drive, Suite 308
Dallas, TX 75243

TELEPHONE: 214-233-6170

SPONSOR: SpectOcular, LLC

You are being asked to participate in a research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. To decide whether or not you want to be part of this research, the purpose, procedures, risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as informed consent. This form also explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The study investigator is the owner, CEO and sole employee of SpectOcular LLC, the study sponsor. The study investigator may make money if the study goes well. There are no plans to share this with people who take part in this study. Please ask the research staff if you have any questions.

The study doctor or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to take home and keep for your records.

Purpose of the Study

You are being asked to participate in a research study to determine whether images of the eye (retina) and related health information can be used to better understand and predict overall health, including heart and brain conditions, as well as detect certain eye diseases. About 5,000 people aged 18 years and older will participate in this research study. Your participation in this study will last for 3 years.

Procedures

If you agree to participate, images of your eye taken as part of your routine clinical care may be used for research. Your medical history and other health information may also be reviewed and obtained from your medical doctors and other healthcare providers involved in your care. You will not undergo any additional imaging or procedures for research purposes.

Risks

The primary risk is loss of confidentiality of your personal health information. No additional medical or physical risks beyond routine care are expected.

Benefits

You will not receive direct benefit from participation. This research may help improve future detection of eye and diseases that affect the whole body.

Alternatives to Participation

This study is for research purposes only so your alternative is to not participate in this study.

New Information

You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

Costs and Compensation

There is no cost to you for participation in this study. You will not receive any compensation for participation in this study.

Artificial Intelligence Disclosure

Your data may be used to develop artificial intelligence (AI) models. These models are for research purposes only and will not be used to guide your medical care.

Data Ownership and Commercial Use

By participating, you agree that your de-identified data, including images, clinical information, and any derived data, may be used for research, development, and potential commercial purposes. You will not receive financial compensation from any future commercial use of this data.

Voluntary Participation

Participation in this study is voluntary. You may choose not to participate or may withdraw your participation at any time without penalty or loss of benefits to which you are otherwise entitled, and without affecting your medical care.

You may withdraw from the study at any time by notifying the study team using the contact information provided below either:

- In writing (for example, email or mailed notice), or
- By contacting the study team by phone

If you choose to withdraw, no new information will be collected about you for research purposes after the date of withdrawal. The effective date of withdrawal will be the date the study team receives your request.

However, information and retinal images that have already been collected and used as part of the research, including data that has been de-identified or incorporated into aggregated datasets, analyses, or machine learning models, cannot be removed or withdrawn.

Data that has been de-identified and integrated into research datasets or analytical models may continue to be used for research purposes and cannot be linked back to you.

Your participation may be stopped without your consent by the study doctor or the FDA for any reason. For example, your participation may be stopped:

- if it is deemed to be in the best interest of your health and welfare.

Employees as Research Subjects

Regarding employees who participate in the study, there will be no privilege given for participating in this research study. Likewise, there will be no penalty or drawbacks associated with not participating. Participation is strictly voluntary and will not be tied to any preferential treatment or promotion within the company.

Confidentiality and Authorization to Collect, Use and Disclose Your Medical Information

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

Under the privacy laws, you have the right to decide who can use your protected health information (called PHI). By signing this form, you authorize the use and disclosure of your protected health information (“PHI”) for research purposes as described in this study.

The information that may be used or disclosed includes:

- Retinal images obtained during your clinical care
- Medical history
- Diagnoses
- Medications
- Laboratory results

- Vital signs
- Imaging studies (including radiology such as CT, MRI, and X-ray)
- Cardiac testing (including echocardiograms and stress tests)
- Procedure reports (including colonoscopy, endoscopy, and other procedures)
- Other relevant health information

This information may be obtained from:

- Your eye care providers
- Your primary care physician
- Other healthcare providers involved in your care
- Hospitals, laboratories, and diagnostic service providers

The study team will know your identity; however, your records will be labeled with a code that is randomly assigned to you. The research staff are the only people who will have this code and its key.

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- SpectOcular LLC and its research team
- Sterling Institutional Review Board (IRB)
- Authorized research personnel and collaborators
- Other doctors, health care professionals or research staff who are involved in the study

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

The purpose of this authorization is to conduct research, including the development and validation of analytical models and artificial intelligence technologies related to eye and whole body health.

This authorization does not have an expiration date.

You may revoke (take away) this authorization at any time by contacting the study team in writing. However, any information already collected and used as part of the research, including data that

has been de-identified or incorporated into datasets, analyses, or machine learning models, cannot be withdrawn.

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 government officials or the Institutional Review Board make sure that the study was conducted properly.

Information disclosed as part of this research may be subject to redisclosure and may no longer be protected under federal privacy regulations.

Contact Information

If you have questions about this study, please contact the study team at SpectOcular:

SpectOcular LLC
11615 Forest Central Drive, Suite 308
Dallas, Texas 75243
E-mail: info@spectocularhealth.com
Phone: 214-233-6170
Fax: 214-241-4947

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

Participant Statement and Authorization

I have read or have had read to me the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I agree to participate voluntarily in this study. I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.

I will receive a signed copy of this form.

All my questions have been answered.

I have not waived any of my legal rights by signing this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

_____ _____
Signature of Witness Date

*A witness is not required unless the participant is unable to read (such as blind or illiterate). If a witness is present, however, the witness must observe the entire informed consent process, including participant signature.